

EXHIBIT 9



Investigation of Deviation Report

SECTION I: Preliminary Investigation Investigation Log No. 07-093

Product Name: Digoxin Tablets 0.125 mg (145) Product Lot No. 70924A1

For confirmed OOS, OOS Log No. N/A

Description of Problem Two tablets of Digoxin tablets 0.125 mg were found with approx. double the thickness from counter channels during packaging/filling operation on packaging line # 405. The incident was noticed by line lead person, Vites Patel, on 11/30/07 at about 3.15 PM during the packaging of bucket numbers 15 & 16. The Packaging Manager, Dilip Joshi and the Director of Packaging, Ashesh Dave were contacted and informed about this incident. Ashesh Dave instructed him to stop the operation immediately. The QA Supervisor was alerted of the incident and the QA Director was then notified.

Impact of deviation on the batch (s): The batch (control # 70924A1) has been put on HOLD by QA.

Prepared by Investigating Department: D. Joshi Date 12-05-07

SECTION II: Investigation, to be prepared by Investigating Director.

Briefly Describe Reason for Investigation: The cause of deviation will be investigated by manufacturing dept.

Assignable Cause(s): Complete table below as per Exhibit A. Or write "EWJ"- Eliminated with Justification. Use this table to document that six categories were addressed to identify the assignable cause.

Category	Cause-First Iteration	Cause-Second Iteration	Cause-Third Iteration
A. Equipment/facility/ utility	X		
B. Human error	EWJ		
C. Natural causes	EWJ		
D. DDI/batch record	EWJ		
E. API, Ingredient or vendor	EWJ		
F. Product/Process/Packaging	EWJ		
G. Other (specify)	EWJ		

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Section III: CROSS FUNCTIONAL TEAM

Investigation Log No: 07-093

Was a cross functional team assembled to assist in identifying the assignable cause and provide input regarding Impact analysis?

☐ No

☒ Yes. List member's name and department below

Team Member Name	Department
Dilip Joshi	Packaging
Eric Cardona	Manufacturing
Dan Bittler	QA

IMPACT ANALYSIS:

Impact on Other Batches and /or products:

The deviation is considered an isolated incident; therefore no other batches are impacted.

Department Head: _____

Name/Signature

Date: 01/24/08

Section IV: CORRECTIVE AND PREVENTIVE ACTION

Describe corrective action(s) and provide an expected completion date

(Attach additional pages if necessary):

As a corrective action, all the tablets that had already been packaged were emptied into bulk containers and a 100% inspection was performed on the entire batch. After the inspection a high level tightened AQL inspection was performed to ensure that the defect tablets have been removed from the batch.

Expected Date of Completion: completed

Describe the action (s) to prevent the recurrence of this deviation. Include both short and long term actions
(Attach additional pages if necessary):

The tablet press operators were trained to remove the tablet deduster and metal detector during start-up the tablets that are produced during machine adjustment can fall directly into the rejection bucket eliminating the possibility of an unacceptable tablet being left on the equipment after adjustments are made.

Expected Date of Completion: completed

Prepared By: _____

Name/Signature

Date: 01/25/08

ACTAVIS TOTOWA LLC.
101 EAST MAIN STREET LITTLE FALLS NJ

Date: 1/8/08

To: **Batch File: Digoxin Tablets, USP 0.125mg (145)**
Batch Number: 70924A

From: Michael Ponzo, Quality Assurance

Subject: Investigation 07-093

On 11/30/07, a packaging operator observed two tablets of the subject batch with approximately double the thickness on the counter channel of packaging line # 405. The lead line operator observed the tablets during the packaging of bucket numbers 15 & 16. The bottles that had already been packaged and the remaining tablets were subsequently placed on hold (H-07-089). Packaging operators were instructed to perform a 100% inspection on the tablets from the hopper (bucket numbers 15 & 16) as well as the two subsequent buckets, numbers 17 & 18. While inspecting bucket number 17, one more tablet was identified, and none were identified in bucket number 18. The remainder of the batch was packaged while operators performed a continuous manual inspection of the tablets as they traveled down the bottle filler channels. While inspecting the final bucket, number 34, two more tablets were identified; bringing the total to five tablets with double the thickness.

Upon notification, the manufacturing department performed a batch record review of the subject batch (See Attachment # 1). Digoxin Tablets, USP 0.125mg are manufactured according to MPR# 14504, revision # 08 and have a batch size of 4.8 million tablets. Manufacturing noted the subject batch was compressed using two tablet presses (press #67, & #71).

Specifications for Digoxin Tablets, USP 0.125mg are as follows:

Weight Range (10 tablets): 1.019g – 1.082g

Thickness Range: 2.0mm – 3.0mm

Hardness Range: 1.0kp – 6.0kp

Every 30 minutes three tablets are sampled from each exit chute of each tablet press and checked for thickness compared to the specifications for the product. Additionally, QA takes 45 samples from each exit chute (1 for each station) at start-up and periodically takes samples while in process to verify weight, thickness, and hardness of each sample. All Start-up and in-process tablet samples from both tablet press machines were found to be within specification (See Attachment # 2)

A review of the finished product testing of the subject batch showed all samples to meet specification for description, identification, friability, assay, content uniformity, dissolution and related substances (See Attachment # 3).

It was noted in the compression data sheet that the press operator had stopped press number 67 and removed the upper and lower punches of the tablet press due to excessive

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Batch File: Digoxin Tablets 0.125mg Batch Number: 70924A

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dust build up on the third day of processing, 11/19/07. When the upper and lower punches were replaced, a new start-up is performed. During start-up the tablet press is re-adjusted to meet the specifications set for the product that is being manufactured. The Manufacturing Manager indicated that the tablets found with double the thickness might have been produced during the re-adjustment at start-up. The possibility that tablets might have gotten stuck in the tablet deduster or metal detector and went unnoticed by the press operator is being considered a possible root cause of the tablets found with double the thickness.

Further review of the compression section of the batch record indicated that tablets from both bucket numbers 17 & 34 were compressed using tablet press number 67. Bucket 17 was filled on 11/19/07 and bucket 34 was filled on 11/20/07 (See Attachment # 4).

A review of the tablet press history was performed. The log indicates that the batch subsequent to the subject batch was also Digoxin Tablets, USP 0.125mg. Manufacturing of this batch started on 11/20/07 and did not indicate tablets manufactured with double the thickness (See Attachment # 5).

An inspection protocol (See Attachment # 6) was issued to have the subject batch 100% inspected in order to remove any tablets that appeared to have double the thickness. The inspection criterion was reviewed with the inspectors prior to the inspection to ensure the acceptability of the product for release to the market. The inspection was completed and a total of 15 tablets with approximately double the thickness were removed from the entire batch. This is in addition to five tablets removed during the packaging operation.

Following the 100% inspection, the QA team conducted a "Tightened" AQL inspection (See Attachment # 7) to ensure that the defect tablets have been removed from the batch. The tightened AQL inspection would require a rejection of the batch if as few as 2 tablets were found to have double tablet thickness. The batch passed the inspection requirements on 1/18/08 (See Attachment # 8 for Inspection Documentation).

#7 was 4/18/08

Based on the inspection results, this batch will be dispositioned to be released.

As a preventative action, tablet press operators were instructed to remove the tablet deduster and metal detector during start-up. With this action the tablets that are produced during machine adjustment can fall directly into the rejection bucket, therefore eliminating the possibility of an unacceptable tablet being left on the equipment after adjustments are made. The deduster and metal detector will be replaced when acceptable limits are achieved.

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Batch File: Digoxin Tablets 0.125mg Batch Number: 70924A

Root Causes Analysis:

Although it cannot be confirmed, the root cause of the deviation appears to be an insufficient set up of the Stokes Tablet Press #67 after the new start-up was granted. The Manufacturing Manager indicated that it is possible some tablets might have got stuck in the tablet deduster or metal detector and went unnoticed by the press operator. These double thick tablets could then have fallen into the accepted tablet containers and not the rejected tablet container once the compression machine was granted start-up approval and compression was re-initiated.

Conclusion:

The 100% inspection performed on the subject batch eliminated any tablets that were found to have double the thickness. This inspection was ultimately verified by a follow-up AQL inspection, supported that there were no double thick tablets remaining in the batch. Both inspections provide support for release of the subject batch.

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01/25/08

Section IV: QA & REGULATORY EVALUATION

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QA Review Investigation for Completeness and Accuracy and preventive action(s) for appropriateness:

☒ Report Accepted☐ Report Unaccepted

Reviewed By: Quality Assurance

Name/ Signature

01/25/08
Date:

The following documents must be filed with regulatory agencies:

~~_____~~
~~_____~~
~~_____~~

☒ QA may proceed with product disposition☐ Regulatory Agency Approval required, QA can't proceed with product disposition

Regulatory Affairs/Quality Compliance approval of Deviation Report

Name/signature

01/25/08
Date:

Section V: PRODUCT DISPOSITION

Recommend Disposition of product (s):

Based on the results of this investigation and the
 100% inspection / AQL inspection this batch is acceptable for repackaging and
 subsequent release for distribution as long as all other release criteria have been met.

Approved By: Head, Quality Assurance:

Name/ Signature

Date:

01/25/08

If additional pages are attached, Number of pages:

60

Number of attachments:

9

EXHIBIT A

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QUESTIONS	CONSIDERATION
Is this a recurring problem	What steps were taken before to resolve Are the conditions the same
A. Is it equipment/laboratory instrument/facility/ utility problem	A.1. Maintenance program inadequate A.2. Malfunction (good maintenance program) A.3. Calibration procedure, ODI or frequency inadequate A.4. Obsolete; requires replacement A.5. Qualification, operation instruction are inadequate A.6. Inadequate equipment/facility design A.7. Environmental (HVAC) A.8. Cross contamination (micro contamination) A.9. Water system failure
B. Is it a human problem	B.1. Inadvertent human error/accident B.2. Job performance problem B.3. Training not given for specific DOI or task B.4. Inadequate training program B.5. Inadequate supervision
C. Is it due to natural causes	C.1. Power failure C.2. Flood C.3. Others-beyond the plant's control
D. Is it a DOI/MOI/batch record problem	D.1. DOI/MOI/batch record format is not operator friendly D.2. DOI/MOI/batch record are not current with practice D.3. Document issuance and control is inadequate D.4. There is no DOI/MOI/form for the task
E. API, ingredient or vendor issue	E.1 Vendor performance problem E.2. MOI need review/revision E.3. Material does not reflect functionality expected E.4. Material was stored improperly E.5. Material was transferred to improper container
F. Product/Process/packageing/test procedure	F.1. Process parameters need to be revised F.2. MOI need revision (specifications are not current) F.3. Formulation needs revision F.4. Container/closure need revision F.5. Labeling/secondary packaging need revision F.6. Test procedure is not reproducible in QC lab

Attachment #1
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JMB
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101 EAST MAIN STREET LITTLE FALLS, NJ 07424 USA

DATE: 12/15/07
TO: Batch File-Digoxin Tablets, USP 0.125mg
Batch 70924A
FROM: Eric Y. Cardona, Manufacturing Manager
SUBJECT: Investigation # 07-093

During the packaging of Digoxin Tablets, USP 0.125mg batch #70924A, the line operator found two tablets on the counter channel that seemed to be double the thickness of an average tablet. After management was informed the packaging operation was stopped.

A review of the compression stage was performed.

Digoxin Tablets, USP 0.125mg batch #70924A was compressed using two tablet presses; press #67 in room #119 and press #71 in room #120. Specifications for Digoxin Tablets, USP 0.125mg are as follows: weight range (1.019g – 1.082g), thickness range (2.0mm – 3.0mm), and hardness range (1.0kp – 6.0kp).

The Compression Data Sheet for press #67 was reviewed and it showed that on 11/19/07, the third day of the compression stage, the operator stopped the machine and removed the upper and lower punches for cleaning due to excessive powder build up. The upper and lower punches were cleaned and set back into press #67, and a new start-up was given to QA.

The Compression Data Sheet for press #71 was reviewed and no deviations or comments were recorded.

All in-process tablet tests performed by manufacturing for weight, thickness and hardness for both machines were checked and all were within acceptable limits.

The QA In-Process Compression Start-Up Data Sheet and the Overcheck Data Sheet for press #67 and #71 were reviewed. A total of 765 tablets were checked for thickness and all were within acceptable limits.

Set-up (Upper and Lower Punches)

When setting-up the upper and lower punches, the pressure from the lower rollers must be decreased. The pressure is decreased by turning a dial which also controls the thickness of the tablets.

This is done to assure that the upper and lower punches don't come in contact of each other when passing through the section of the pressure rollers without any material in the dies. If the pressure is left on the pressure rollers and there's no material in the dies, the upper and lower punches can be damaged. Even if the punches are rotated around with the hand wheel.

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6/25/08

An interview with the compression department supervisor was performed to discuss how a thicker tablet can end up in a finished product drum. **(When the room and equipment has been set-up for manufacturing, the tablet deduster and metal detector are placed in line under the tablet discharge chute.)** During the start-up of a product batch, machine adjustments are made to achieve the weight, thickness and hardness specified for the tablets in the MPR. The tablets are then checked. If they are outside acceptable limits the machine is again adjusted to bring tablets within acceptable limits. All tablets during start-up adjustment are vibrated through the tablet deduster and metal detector into a labeled reject bucket. After the start-up adjustment is completed, the reject bucket is placed aside and another bucket is used for acceptable tablets. The press, tablet deduster and metal detector are then inspected to assure that no tablets during adjustment are present. There is a possibility that a tablet or several tablets could have gotten stuck in the tablet deduster or metal detector and went unnoticed by the operator and QA, and actually fell into the acceptable product bucket.

As a preventative action, when adjusting the tablet press at start-up, in order to achieve acceptable tablets, the operator will be instructed that the tablet deduster and metal detector be removed from under the discharge chute of the tablet press. The tablets being produced during the machine adjustments can then fall directly into the reject bucket. This will eliminate the possibility of an unacceptable tablet being left on the equipment after adjustments are made and acceptable limits are achieved.

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MPR #: 14504	Rev #: 08	Effective Date: 6/16/06	Batch #: 70924A
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			
Batch Size: 4,800,000 Tablets			

OPERATING INSTRUCTIONS SECTION V
PRODUCT RECONCILIATION AND YIELD

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1. Blending Stage:

a. Final Blend Weight	<u>503.25</u> kg
b. Quantity Rejected / Destroyed	<u>0.350</u> kg
c. Quantity of Samples taken (Step # 30, Page # 15)	<u>0.007</u> kg
d. Total Weight (a + b + c)	<u>503.607</u> kg
e. Theoretical Weight	<u>504.0</u> kg
f. Percent Reconciled (d / e) x 100	<u>99.92</u> %
g. Percent Yield (a / e) x 100	<u>99.85</u> %

2. Compression Stage:

h. Usable Tablets Produced	<u>499.240</u> kg
i. Quantity Rejected / Destroyed	<u>1.560</u> kg
j. Quantity of Samples taken (Step # 4, Page # 22)	<u>0.200</u> kg
k. Total Weight (h + i + j)	<u>501.000</u> kg
l. Percent Reconciled (k / a) x 100	<u>99.55</u> %
m. Usable Compressed Tablets (h / 105 mg) x 1,000,000	<u>4,754,666</u> Tablets
n. Theoretical Batch Size	<u>4,800,000</u> Tablets
o. Percent Yield (m / n) x 100	<u>99.06</u> %

NOTE: The Reconciliation should be within 97.0% - 101.0% and the yield should be within 95.0% - 101.0%. If the Reconciliation or yield is outside the range, notify the Department Supervisor and determine the cause of the variance.

REMARKS:

Done By: <u>EV</u>	Date: <u>11/21/07</u>	Checked By: <u>K.Y.P</u>	Date: <u>11/21/07</u>
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COMPRESSION DATA SHEET

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Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg Batch #: 70924A Date: 11/17/07

Tablet Press Id: 607 Hardness Tester Id: 264 Thickness Gauge Id: 979 Scale Id: 929

Target Weight (1 Tablet): 105.0 mg

Thickness: 2.0 - 3.0 mm

Target Weight (10 Tablets): 1.050 g

Hardness: 1.0 - 6.0 KP

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Every 30 minutes, check ten (10) tablets for aggregate weight and appearance and three (3) tablets for hardness and thickness from each exit chute of the tablet press and compare results to the above product specifications. Record RPM of tablet press upon stabilization of press after every startup, and speed changes

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
PM	MIC	start	up						SPG										
3:45	1.057	OK	2.73	2.73	2.71	3.6	3.4	3.8	SPG	PM	1.048	OK	2.70	2.67	2.68	3.4	3.5	4.0	SPG
	Exit	sy	check						SPG										
	MIC	stop	FOR QA	Approval					SPG										
	MIC	start	AFTER QA	Approval					SPG										
PM	1.065	OK	2.72	2.70	2.74	4.4	4.1	4.0	SPG	PM	1.055	OK	2.71	2.74	2.69	3.5	3.9	3.7	SPG
4:50	MIC	stop	FOR END OF shift						SPG										
	MIC	start	up	11/18/07					AV										
7:15 AM	1.047	OK	2.72	2.70	2.74	3.9	4.0	3.3	AV	7:15 AM	1.060	OK	2.71	2.72	2.72	3.5	3.5	3.9	AV
Date	SPG 11/18/07	AV				Comments:													
Time	PM 4:35	AM 7:30																	
RPM	22	22																	

*App = Appearance

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11/18/07
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COMPRESSION DATA SHEET

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Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/18/07
11/19/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

COPY

Front Exit Chute

Rear Exit Chute

Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm	Hardness 1.0 - 6.0 KP	Init
7:00					
7:45	1.060	OK	2.65 2.69 2.66	4.3 4.0 4.5	SKR
8:15	1.055	OK	2.61 2.66 2.68	5.0 4.0 4.7	SKR
8:45	1.063	OK	2.69 2.61 2.66	4.9 4.4 4.8	SKR
9:00	MIC STOP		END OF RUN		SKR
	MIC Start		11/19/07		AV
7:40	1.057	OK	2.70 2.66 2.68	4.1 4.5 4.3	AV
8:10	1.041	OK	2.71 2.57 2.77	3.3 2.6 2.7	AV
8:40	1.046	OK	2.67 2.66 2.65	5.5 5.1 4.8	AV
9:10	1.064	OK	2.69 2.67 2.75	5.0 4.0 4.4	AV
9:40	1.057	OK	2.65 2.62 2.64	4.2 4.6 5.0	AV
10:10	1.056	OK	2.61 2.75 2.63	4.8 3.2 4.9	AV
10:28	MIC STOP		FOR BREAK		AV
10:55	1.057	OK	2.65 2.63 2.66	4.8 4.9 5.4	AV
11:25	1.044	OK	2.80 2.77 2.60	3.4 3.8 4.9	AV

Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm	Hardness 1.0 - 6.0 KP	Init
7:00					
7:45	1.058	OK	2.69 2.66 2.71	4.9 4.3 4.4	SKR
8:15	1.053	OK	2.66 2.69 2.68	4.7 4.4 4.6	SKR
8:45	1.060	OK	2.69 2.61 2.66	4.4 3.6 4.1	SKR
7:40	1.068	OK	2.69 2.73 2.72	5.1 5.6 3.7	AV
8:10	1.067	OK	2.63 2.66 2.64	4.5 4.1 4.9	AV
8:40	1.053	OK	2.74 2.63 2.70	3.0 4.5 4.7	AV
9:10	1.056	OK	2.61 2.66 2.61	4.4 4.4 4.7	AV
9:40	1.044	OK	2.61 2.62 2.77	4.4 4.5 3.5	AV
10:10	1.052	OK	2.73 2.68 2.71	3.1 4.3 3.1	AV
10:55	1.064	OK	2.65 2.77 2.64	4.9 3.1 2.7	AV
11:25	1.046	OK	2.61 2.58 2.59	3.0 4.0 4.5	AV

Date	11/18/07	11/19/07			
Time	7:00	8:00			
RPM	22	22			

Comments:

*App = Appearance

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COMPRESSION DATA SHEET

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Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/19/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
11:55 ^{AM}	1.059	OK	2.75	2.80	2.63	3.6	3.0	5.2	AV	11:55 ^{AM}	1.044	OK	2.55	2.66	2.55	4.9	3.6	4.8	AV
12:25 ^{PM}	1.053	OK	2.62	2.68	2.73	4.7	5.7	3.2	AV	12:25 ^{PM}	1.053	OK	2.61	2.59	2.59	5.4	5.3	5.7	AV
12:55	1.051	OK	2.55	2.75	2.57	4.4	3.2	5.0	AV	12:55	1.045	OK	2.73	2.57	2.55	4.2	5.1	5.4	AV
1:25	1.040	OK	2.55	2.69	2.77	3.1	4.8	3.0	AV	1:25	1.042	OK	2.65	2.69	2.74	3.8	4.3	3.5	AV
1:28	m/c	stop	FOR Wash Bowl						AV										
2:05	1.060	OK	2.62	2.63	2.64	4.7	5.5	6.0	AV	2:05	1.051	OK	2.73	2.69	2.57	3.7	3.9	5.5	AV
2:30	m/c	stop							AV										
	m/c	start							pmc										
6:00 ^{PM}	1.056	OK	2.66	2.66	2.67	4.7	4.2	4.0	pmc	6:00 ^{PM}	1.058	OK	2.66	2.67	2.65	4.5	4.4	5.0	pmc
	exit sy	check							pmr										
	m/c	stop	SA APPAR L						pmr										
	m/c	start	SA APPAR L						pmr										
7:20 ^{PM}	1.050	OK	2.63	2.64	2.66	4.2	4.6	4.7	pmr	7:20 ^{PM}	1.048	OK	2.62	2.64	2.67	4.2	4.2	4.0	pmr
7:48	m/c	slow	SAV other det						pmr										
Date	11/19/07								Comments: * Stopped, removed & cleaned upper & lower punches due to excessive excessive build-up of powder. EV 11/19/07										
Time	12:20 ^{PM}																		
RPM	22																		

*App = Appearance

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COMPRESSION DATA SHEET

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Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/20/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
7:40 AM	1.053	OK	2.66	2.69	2.67	3.9	3.7	4.3	AV	7:40 AM	1.049	OK	2.66	2.69	2.67	3.7	3.8	4.0	AV
8:10	1.064	OK	2.68	2.73	2.66	3.8	3.7	3.5	AV	8:10	1.063	OK	2.69	2.71	2.69	3.3	4.7	3.2	AV
8:40	1.063	OK	2.71	2.75	2.73	3.1	3.3	3.8	AV	8:40	1.040	OK	2.66	2.65	2.61	3.4	4.0	4.1	AV
9:10	1.060	OK	2.77	2.74	2.68	3.0	4.6	4.3	AV	9:10	1.041	OK	2.69	2.62	2.64	3.5	4.5	3.8	AV
9:40	1.052	OK	2.61	2.66	2.65	4.4	5.3	4.4	AV	9:40	1.057	OK	2.66	2.70	2.69	4.8	4.7	4.2	AV
10:10	1.051	OK	2.64	2.70	2.68	3.4	5.3	4.3	AV	10:10	1.047	OK	2.64	2.73	2.65	4.1	3.1	3.8	AV
10:28	m/c STOP For Break								AV										
10:55	1.061	OK	2.69	2.63	2.67	4.5	5.2	4.7	AV	10:55	1.061	OK	2.70	2.64	2.69	3.5	4.5	3.8	AV
11:25	1.059	OK	2.69	2.69	2.71	4.0	4.1	4.0	AV	11:25	1.060	OK	2.66	2.69	2.67	4.7	4.1	4.9	AV
11:55	1.045	OK	2.65	2.67	2.69	3.8	5.1	5.0	AV	11:55	1.053	OK	2.67	2.75	2.64	4.0	3.2	5.0	AV
12:25 PM	1.049	OK	2.62	2.61	2.67	4.0	4.4	3.6	AV	12:25	1.044	OK	2.67	2.64	2.61	4.6	3.8	3.0	AV
12:55	1.041	OK	2.57	2.60	2.61	4.5	4.9	4.2	AV	12:55	1.042	OK	2.64	2.65	2.66	4.2	4.6	4.5	AV
1:25	1.049	OK	2.63	2.61	2.64	3.8	4.1	4.0	AV	1:25	1.040	OK	2.60	2.63	2.67	4.0	4.1	4.6	AV
1:30	m/c STOP End of Batch								AV										
Date	11/20/07								Comments:										
Time	8:00 AM																		
RPM	22																		

*App = Appearance

<14504-08>

ACTAV 000003331

11/20/07
11:55 AM
11/20/07

Amide Pharmaceutical, Inc.
QA In-Process Compression Start Up Data Sheet

COPY

Product: **Digoxin Tablets, 0.125 mg** Batch Number: **70924A**
 Number of Stations: **45** Side: **FRONT**
 Appearance: **A** MPR #: **14504-08**
 Specifications
 Weight (Th. 0.105 g) Thickness Hardness
 (0.097 - 0.113) g (2.00 - 3.00) mm (1.0 - 6.0) kp
 Compression Data Sheet signed / Equipment cleared Verified By: **Sam** Date: **11/17/07**

	Weight	Thickness	Hardness
1	0.105	2.70	3.3
2	0.106	2.74	3.7
3	0.108	2.69	3.2
4	0.107	2.71	3.3
5	0.107	2.73	4.6
6	0.106	2.74	4.2
7	0.107	2.73	3.4
8	0.107	2.72	3.9
9	0.106	2.74	3.3
10	0.105	2.71	3.5
11	0.107	2.79	3.8
12	0.106	2.71	4.1
13	0.104	2.74	3.3
14	0.107	2.71	3.9
15	0.106	2.71	3.7
16	0.107	2.72	3.6
17	0.105	2.75	3.6
18	0.107	2.71	3.8
19	0.106	2.71	3.7
20	0.107	2.75	3.8
21	0.106	2.70	3.7
22	0.108	2.71	3.9
23	0.105	2.72	3.6
24	0.107	2.76	3.6
25	0.106	2.73	3.8

	Weight	Thickness	Hardness
26	0.106	2.75	3.6
27	0.104	2.79	3.9
28	0.108	2.76	3.4
29	0.106	2.74	3.4
30	0.104	2.76	3.6
31	0.104	2.73	3.4
32	0.105	2.70	3.3
33	0.106	2.69	3.7
34	0.106	2.68	3.5
35	0.105	2.76	3.1
36	0.106	2.74	3.7
37	0.104	2.76	4.3
38	0.106	2.74	3.7
39	0.104	2.75	3.3
40	0.107	2.70	3.5
41	0.107	2.74	4.6
42	0.105	2.71	3.8
43	0.107	2.73	3.0
44	0.105	2.73	3.5
45	0.107	2.71	3.9
46			
47	N/A		Sam
48			11/20/07
49			
50			

Disposition: Pass
 Analyzed By: Sam
 Reviewed By: Sam

Time: 4:25 pm
 Date: 11/17/07
 Date: 11/20/07

Comments: N/A Sam 11/20/07

Digoxin 0.125 mg Data F.09

Confidential

ACTAV 000003332

Amide Pharmaceutical, Inc.
QA In-Process Compression Start Up Data Sheet

COPY

Product: Digoxin Tablets, 0.125 mg		Batch Number: 70924A
Press #: 67	Number of Stations: 45	Side: REAR
Appearance: A		MPR #: 14504-08
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared		Verified By: <u>Sam</u> Date: <u>11/17/07</u>

	Weight	Thickness	Hardness
1	0.106	2.68	4.3
2	0.107	2.72	3.8
3	0.106	2.74	3.8
4	0.107	2.69	4.3
5	0.106	2.70	4.0
6	0.106	2.72	4.2
7	0.105	2.72	3.8
8	0.105	2.73	3.6
9	0.107	2.73	4.3
10	0.108	2.75	3.8
11	0.105	2.73	4.3
12	0.107	2.73	4.3
13	0.108	2.72	4.3
14	0.106	2.72	4.6
15	0.108	2.76	4.3
16	0.108	2.72	4.0
17	0.106	2.76	4.2
18	0.107	2.73	3.9
19	0.107	2.73	4.3
20	0.107	2.71	4.1
21	0.107	2.71	3.5
22	0.108	2.70	4.3
23	0.107	2.71	3.7
24	0.106	2.78	4.1
25	0.105	2.75	3.5

	Weight	Thickness	Hardness
26	0.106	2.73	4.5
27	0.108	2.70	4.4
28	0.107	2.69	4.1
29	0.106	2.70	3.6
30	0.105	2.73	3.5
31	0.105	2.72	4.1
32	0.104	2.71	3.5
33	0.107	2.69	4.1
34	0.106	2.70	3.7
35	0.105	2.70	3.8
36	0.108	2.72	3.8
37	0.105	2.70	4.0
38	0.106	2.72	4.4
39	0.108	2.68	3.8
40	0.106	2.70	4.6
41	0.107	2.72	3.8
42	0.105	2.75	4.3
43	0.106	2.70	3.9
44	0.107	2.70	4.5
45	0.106	2.72	3.9
46			
47	N/A		Sam
48			11/20/07
49			
50			

Disposition: Pass
 Analyzed By: Sam
 Reviewed By: Sam

Time: 4:25 pm
 Date: 11/17/07
 Date: 11/20/07

Comments: N/A Sam 11/28/07

Digoxin 0.125 mg Data R.00

Amide Pharmaceutical, Inc.
QA In-Process Compression Start Up Data Sheet

COPY

Product: Digoxin Tablets, 0.125 mg		Batch Number: 70924A
Press #: 67	Number of Stations: 45	Side: FRONT
Appearance: A	MPR #: 14504-08	
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared Verified By: MMR Date: 11/19/07		

	Weight	Thickness	Hardness
1	0.104	2.65	4.1
2	0.105	2.65	3.5
3	0.106	2.68	4.2
4	0.103	2.66	3.9
5	0.104	2.64	4.0
6	0.107	2.65	3.8
7	0.105	2.69	3.5
8	0.104	2.67	4.2
9	0.106	2.64	3.5
10	0.105	2.62	3.7
11	0.107	2.65	4.1
12	0.104	2.66	3.8
13	0.108	2.63	3.4
14	0.105	2.61	3.7
15	0.106	2.65	3.6
16	0.105	2.64	3.8
17	0.104	2.62	4.0
18	0.106	2.66	3.4
19	0.103	2.62	4.1
20	0.105	2.66	4.2
21	0.104	2.61	4.6
22	0.107	2.63	4.2
23	0.106	2.64	3.6
24	0.105	2.66	4.3
25	0.107	2.65	4.1

	Weight	Thickness	Hardness
26	0.104	2.63	3.3
27	0.105	2.66	3.9
28	0.103	2.68	4.2
29	0.104	2.64	3.5
30	0.106	2.63	3.7
31	0.105	2.65	3.7
32	0.107	2.67	4.1
33	0.103	2.64	4.2
34	0.105	2.65	4.0
35	0.106	2.70	4.5
36	0.104	2.65	4.6
37	0.105	2.64	3.9
38	0.103	2.68	3.8
39	0.106	2.67	3.6
40	0.105	2.62	4.1
41	0.103	2.65	3.9
42	0.106	2.63	3.5
43	0.105	2.60	3.8
44	0.104	2.59	4.3
45	0.105	2.64	3.7
46			
47			Scm
48	N/A		11/20/07
49			
50			

Disposition: Pass
Analyzed By: MMR
Reviewed By: Scm

Time: 6:55 PM
Date: 11/19/07
Date: 11/20/07

Comments: M/c stopped by removing & cleaning
top & lower punch due to the
extensive build up of powder Scm 11/19/07
Scm 11/19/07

Digoxin 0.125 mg-Data.F.00

Amide Pharmaceutical, Inc.
QA In-Process Compression Start Up Data Sheet

COPY
p. 19/61
Sub

Product: Digoxin Tablets, 0.125 mg		Batch Number: 70924A of 108
Press #: 67	Number of Stations: 45	Side: REAR
Appearance: A		MPR #: 14504-08
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared Verified By: <u>mmr</u> Date: <u>11/19/07</u>		

	Weight	Thickness	Hardness
1	0.105	2.72	4.1
2	0.102	2.64	3.7
3	0.103	2.66	4.1
4	0.104	2.70	4.2
5	0.106	2.69	4.4
6	0.105	2.71	4.0
7	0.106	2.70	3.8
8	0.105	2.68	3.6
9	0.102	2.71	3.8
10	0.107	2.69	3.5
11	0.105	2.71	4.4
12	0.107	2.71	3.8
13	0.104	2.71	4.0
14	0.103	2.69	4.3
15	0.105	2.68	3.7
16	0.104	2.71	4.3
17	0.106	2.73	3.9
18	0.105	2.70	3.3
19	0.104	2.69	4.1
20	0.108	2.69	3.8
21	0.106	2.71	4.1
22	0.105	2.68	3.8
23	0.104	2.66	3.7
24	0.106	2.69	4.2
25	0.105	2.68	3.9

	Weight	Thickness	Hardness
26	0.103	2.70	3.4
27	0.105	2.72	3.9
28	0.107	2.70	4.4
29	0.104	2.67	4.0
30	0.104	2.72	3.5
31	0.105	2.67	3.9
32	0.103	2.66	4.1
33	0.106	2.65	3.2
34	0.105	2.67	3.8
35	0.107	2.70	3.7
36	0.104	2.68	3.3
37	0.105	2.66	3.6
38	0.103	2.71	3.9
39	0.105	2.65	4.0
40	0.106	2.67	3.6
41	0.103	2.73	3.7
42	0.105	2.67	3.7
43	0.104	2.65	4.1
44	0.107	2.68	4.0
45	0.105	2.65	4.2
46			
47			Scm
48	N/A		11/20/07
49			
50			

Disposition: Pass
Analyzed By: mmr
Reviewed By: Scm

Time: 6:55 AM PM
Date: 11/19/07
Date: 11/20/07

Comments: N/A - Scm 11/19/07

Digoxin 0.125 mg Data R.00

Confidential

AMIDE PHARMACEUTICAL, INC.
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924APRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE FrontTHEO. 0.105gmRANGE 0.097 ---- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:28 AM	0.103	0.109	0.106	0.108	0.105	0.106	0.105	0.107	0.106	0.105	P	Sam ASR
11/18/07	8:20 AM	0.105	0.102	0.103	0.103	0.103	0.102	0.102	0.102	0.105	0.102	P	Sam ASR
11/18/07	11:30 AM	0.104	0.103	0.104	0.105	0.103	0.103	0.106	0.105	0.102	0.105	P	Sam ASR
11/18/07	12:39 PM	0.102	0.103	0.104	0.106	0.103	0.103	0.105	0.106	0.104	0.105	P	Sam ASR
11/18/07	1:30 PM	0.108	0.102	0.104	0.106	0.105	0.106	0.103	0.104	0.106	0.110	P	Sam ASR
11/18/07	2:30 PM	0.106	0.109	0.105	0.107	0.105	0.106	0.107	0.107	0.103	0.105	P	Sam ASR
11/18/07	2:30 PM	0.105	0.106	0.105	0.105	0.105	0.103	0.103	0.108	0.106	0.105	P	del
11/18/07	4:10 PM	0.106	0.105	0.106	0.107	0.106	0.105	0.105	0.106	0.105	0.106	P	SLU
11/18/07 11/19/07	7:50 AM	0.104	0.105	0.110	0.106	0.105	0.105	0.105	0.104	0.106	0.106	P	Sam ASR
11/19/07	8:50 AM	0.103	0.110	0.102	0.103	0.102	0.103	0.107	0.102	0.106	0.104	P	Sam ASR
11/19/07	9:50 AM	0.106	0.104	0.107	0.106	0.109	0.106	0.108	0.106	0.108	0.106	P	Sam ASR
11/19/07	11:00 AM	0.104	0.101	0.102	0.107	0.103	0.105	0.102	0.103	0.104	0.102	P	QUM

REV SamDATE 11/20/0711/20/07
0.105
0.106
0.107

ACTAV 000003336

Confidential

Amide Pharmaceutical, Inc.
QA IN - PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mgBATCH 70924APRESS NO 67SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE (2.0 --- 3.0)mm					RANGE (1.0 ----- 6.0) kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:20Am	2.69	2.72	2.76	2.75	2.75	3.8	3.9	3.6	3.1	4.3	P	Scm ASR
11/18/07	8:20Am	2.68	2.66	2.71	2.69	2.65	3.6	3.6	3.2	3.2	3.4	P	Scm ASR
11/18/07	11:38Am	2.68	2.68	2.69	2.70	2.75	3.4	3.2	3.1	3.6	3.0	P	Scm ASR
11/18/07	12:30Pm	2.66	2.62	2.67	2.61	2.80	3.0	4.2	4.5	2.8	3.2	P	Scm ASR
11/18/07	1:30Pm	2.67	2.64	2.66	2.63	2.63	4.4	4.0	3.6	4.6	5.0	P	Scm ASR
11/18/07	2:30Pm	2.63	2.61	2.64	2.67	2.63	5.1	5.3	4.4	4.8	5.1	P	Scm ASR
11/18/07	3:30Pm	2.64	2.69	2.64	2.64	2.70	4.5	4.8	5.0	4.7	4.7	P	Scm ASR
11/18/07	4:00Pm	2.64	2.72	2.68	2.65	2.70	5.7	5.4	5.0	4.9	5.8	P	Scm ASR
11/19/07	7:50Am	2.61	2.68	2.64	2.70	2.71	3.8	3.8	4.6	3.9	4.6	P	Scm ASR
11/19/07	8:50Am	2.55	2.64	2.59	2.67	2.64	4.2	3.2	4.3	3.0	2.6	P	Scm ASR
11/19/07	9:50Am	2.65	2.66	2.67	2.89	2.64	3.4	3.3	3.9	4.0	4.5	P	Scm ASR
11/19/07	11:09Am	2.79	2.69	2.71	2.83	2.70	4.5	3.3	3.4	3.0	3.1	P	Scm ASR

REV. BY ScmDATE 11/20/07

COPY

11/20/07

ACTAV 000002598

Confidential

AMIDE PHARMACEUTICAL, INC
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924APRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE RearTHEO. 0.105gmRANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:20 AM	0.106	0.108	0.106	0.107	0.106	0.107	0.108	0.105	0.106	0.106	P	Sam
11/18/07	8:20 AM	0.104	0.101	0.107	0.104	0.106	0.106	0.106	0.105	0.104	0.106	P	Sam
11/18/07	11:30 AM	0.102	0.103	0.106	0.105	0.104	0.108	0.105	0.104	0.106	0.104	P	Sam
11/18/07	12:30 PM	0.104	0.104	0.104	0.106	0.104	0.105	0.105	0.105	0.104	0.108	P	Sam
11/18/07	1:30 PM	0.105	0.105	0.104	0.104	0.107	0.105	0.106	0.106	0.105	0.104	P	Sam
11/18/07	4:30 PM	0.104	0.103	0.106	0.104	0.103	0.107	0.105	0.104	0.104	0.105	P	Sam
11/18/07	3:30 PM	0.104	0.102	0.105	0.103	0.104	0.103	0.104	0.103	0.106	0.105	P	Sam
11/18/07	4:00 PM	0.103	0.104	0.102	0.103	0.104	0.105	0.104	0.104	0.107	0.104	P	Sam
11/19/07	7:50 AM	0.107	0.106	0.108	0.108	0.105	0.106	0.103	0.106	0.105	0.107	P	Sam
11/19/07	8:50 AM	0.103	0.105	0.104	0.103	0.102	0.104	0.105	0.105	0.105	0.104	P	Sam
11/19/07	9:50 AM	0.107	0.105	0.105	0.105	0.104	0.105	0.107	0.105	0.104	0.105	P	Sam
11/19/07	11:00 AM	0.104	0.105	0.109	0.106	0.105	0.105	0.104	0.105	0.105	0.107	P	Sam

REV SamDATE 11/20/07

0.105
0.106
0.107
0.108
0.109
0.110
0.111
0.112
0.113

ACTAV 00002589

Confidential

QA IN-PROCESS COMPRESSION OVER-CHECK DATA SHEET

THICKNESS/ HARDNESS

PRODUCT Digoxin Tablets 0.125 mg

COPY

Batch 70924APRESS NO 67SIDE Rear

		THICKNESS					HARDNESS						
		RANGE (2.0 ---- 3.0)mm					RANGE (1.0---6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:10 AM	2.76	2.73	2.77	2.76	2.77	3.8	3.6	3.4	3.8	3.9	P	Sam ASR
11/18/07	8:20 AM	2.68	2.69	2.70	2.73	2.69	4.0	4.1	4.0	4.0	3.9	P	Sam ASR
11/18/07	11:30 AM	2.68	2.66	2.81	2.71	2.69	3.8	4.3	2.9	4.1	4.2	P	Sam ASR
11/18/07	12:30 PM	2.60	2.62	2.75	2.61	2.60	5.4	5.4	4.9	4.9	5.4	P	Sam ASR
11/18/07	1:30 PM	2.60	2.63	2.67	2.76	2.62	3.1	5.4	5.1	5.0	4.8	P	Sam ASR
11/18/07	2:20 PM	2.65	2.66	2.64	2.67	2.62	3.2	4.7	4.9	4.9	4.6	P	Sam ASR
11/18/07	3:30 PM	2.59	2.64	2.61	2.63	2.60	4.9	4.1	4.3	4.7	4.4	P	Sam ASR
11/18/07	4:00 PM	2.58	2.59	2.59	2.61	2.61	4.6	5.5	5.2	4.8	5.5	P	Sam ASR
11/19/07	7:50 AM	2.65	2.86	2.64	2.64	2.66	4.5	2.9	4.1	4.6	4.9	P	Sam ASR
11/19/07	6:50 PM	2.67	2.63	2.58	2.60	2.71	4.1	4.3	2.5	4.4	4.3	P	Sam ASR
11/19/07	9:15 PM	2.62	2.64	2.63	2.77	2.64	3.6	4.8	3.6	4.3	5.0	P	Sam ASR
11/19/07	11:00 PM	2.70	2.68	2.62	2.80	2.82	3.1	2.9	3.0	4.9	3.3	P	Sam ASR

REV. BY SamDATE 11/20/07p.23 of 67
01/21/08

ACTAV 000002600

Confidential

AMIDE PHARMACEUTICAL, INC
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924APRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE FrontTHEO. 0.105gmRANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	12:00 pm	0.107	0.103	0.105	0.104	0.109	0.105	0.105	0.102	0.108	0.106	P	Sam
11/19/07	1:00 pm	0.103	0.105	0.108	0.103	0.108	0.105	0.103	0.104	0.103	0.104	P	Qum
11/19/07	2:10 pm	0.107	0.106	0.109	0.103	0.109	0.108	0.106	0.104	0.105	0.110	P	Sam
11/20/07	7:45 AM	0.106	0.102	0.111	0.106	0.105	0.107	0.104	0.109	0.105	0.109	P	Qum
11/20/07	8:45 am	0.106	0.104	0.103	0.108	0.105	0.106	0.105	0.106	0.106	0.104	P	Sam
11/20/07	9:50 am	0.105	0.106	0.104	0.107	0.103	0.105	0.104	0.105	0.108	0.106	P	Sam
11/20/07	11:00 AM	0.106	0.105	0.105	0.104	0.103	0.103	0.106	0.106	0.105	0.107	P	Sam
11/20/07	12:00 pm	0.103	0.104	0.104	0.104	0.105	0.105	0.104	0.104	0.105	0.104	P	Sam
11/20/07	1:00 pm	0.105	0.105	0.104	0.104	0.105	0.103	0.104	0.106	0.104	0.105	P	Qum
					N/A			Sam	11/20/07				

REV SamDATE 11/20/07

* Mic stopped, removed & cleaned cup
& Low punches due to the excessive
build up of powder - Sam 11/19/07

ACTAV 000002601

COPY

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Amide Pharmaceutical, Inc.
QA IN-PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mgCOPY BATCH 70924APRESS NO 67SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE (2.0 --- 3.0)mm					RANGE (1.0 ----- 6.0) kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	12:30 PM	2.60	2.63	2.61	2.71	2.78	4.2	4.1	3.0	3.7	4.7	P	Scm ASR
11/19/07	1:00 PM	2.57	2.58	2.60	2.60	2.74	5.1	5.1	3.6	4.3	4.6	P	QUM
11/19/07	2:10 PM	2.64	2.60	2.60	2.63	2.61	5.3	5.0	4.8	4.3	4.1	P	Scm
11/20/07	7:45 AM	2.72	2.65	2.70	2.71	2.69	4.3	4.8	4.6	4.0	4.2	P	QUM
11/20/07	8:45 AM	2.72	2.75	2.68	2.68	2.67	3.5	4.5	3.6	3.5	4.5	P	Scm ASR
11/20/07	9:50 AM	2.69	2.72	2.69	2.76	2.70	4.8	4.0	4.3	5.0	5.2	P	mmr Scm
11/20/07	11:00 AM	2.66	2.68	2.70	2.67	2.64	5.4	3.6	4.5	4.4	4.2	P	ASR
11/20/07	12:02 PM	2.67	2.68	2.73	2.62	2.68	4.7	3.9	4.5	5.0	4.0	P	Scm ASR
11/20/07	1:00 PM	2.62	2.61	2.67	2.68	2.67	4.9	4.4	4.4	4.6	4.8	P	QUM
								Scm					
				N/A						11/20/07			

REV. BY ScmDATE 11/20/07

COPY

ACTAV 000002602

Confidential

AMIDE PHARMACEUTICAL, INC
QA IN-PROCESS COMPRESSION OVERCHECK DATA SHEET

WEIGHT

BATCH 70924HPRODUCT Digoxin Tablets 0.125 mg

COPY

PRESS.NO 67SIDE RearTHEO. 0.105gmRANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	12:00 PM	0.105	0.107	0.102	0.104	0.104	0.110	0.102	0.108	0.103	0.104	P	Sam
11/19/07	1:00 PM	0.103	0.105	0.104	0.103	0.105	0.102	0.103	0.102	0.103	0.104	P	Sam
11/19/07	2:10 PM	0.109	0.106	0.104	0.103	0.103	0.106	0.105	0.103	0.103	0.102	P	Sam
11/20/07	7:45 AM	0.102	0.108	0.102	0.101	0.104	0.104	0.108	0.104	0.106	0.110	P	Sam
11/20/07	8:45 PM	0.108	0.103	0.107	0.101	0.104	0.105	0.105	0.104	0.103	0.105	P	Sam
11/20/07	9:50 PM	0.106	0.104	0.108	0.105	0.104	0.106	0.105	0.106	0.107	0.105	P	Sam
11/20/07	11:00 AM	0.106	0.103	0.104	0.104	0.105	0.109	0.103	0.106	0.105	0.104	P	Sam
11/20/07	12:00 PM	0.105	0.104	0.106	0.105	0.104	0.110	0.107	0.105	0.105	0.105	P	Sam
11/20/07	1:00 PM	0.102	0.103	0.105	0.105	0.104	0.104	0.103	0.106	0.104	0.105	P	Sam
								Sam					
					N/A			11/20/07					

REV SamDATE 11/20/07

01/17/08
 01/17/08
 01/17/08

ACTAV 000002624

THICKNESS/ HARDNESS

COPY

PRESS NO 67

SIDE Rear

		THICKNESS					HARDNESS							
		RANGE (2.0 ---- 3.0)mm					RANGE (1.0---6.0)kp							
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY	
11/19/07 11/19/07	12:00 PM	2.74	2.56	2.56	2.76	2.69	4.8	4.4	5.2	2.9	4.3	P	Scm ASR	
11/19/07	1:00 PM	2.69	2.64	2.70	2.74	2.55	5.5	5.4	5.8	2.9	3.2	P	NM	
11/19/07	2:10 PM	2.67	2.54	2.55	2.56	2.56	5.2	5.1	5.2	5.2	3.4	P	Scm	
11/20/07	7:45 AM	2.67	2.67	2.67	2.68	2.63	3.7	2.63 ^{3.4}	2.63 ^{3.9}	4.2	3.9	P	NM	
11/20/07	8:45 AM	2.60	2.63	2.70	2.66	2.61	3.6	3.1	3.6	4.0	3.8	P	NM ASR	
11/20/07	9:50 AM	2.65	2.68	2.64	2.65	2.67	5.0	4.9	4.6	5.0	5.2	P	NM	
11/20/07	11:00 AM	2.67	2.68	2.65	2.69	2.68	4.5	4.2	5.3	4.7	4.7	P	Scm ASR	
11/20/07	12:00 PM	2.74	2.70	2.65	2.75	2.69	4.0	4.7	4.1	5.0	3.8	P	Scm ASR	
11/20/07	1:00 PM	2.75	2.77	2.69	2.64	2.59	4.3	5.1	4.5	3.9	3.8	P	NM	
					N/A									

Scm 11/20/07

COPY

REV. BY Scm

DATE 11/20/57

1.27 of 67
A. 25/23

COPY

JMS
01/27/0826
11/27/07
JMS
01/27/08AMIDE PHARMACEUTICAL, INC.
QA IN PROCESS COMPRESSION OVERCHECK DATA SHEET

COPY

APPEARANCE

PRODUCT Digoxin Tablets 0.125 mgBatch 70924A

PRESS NO. <u>67</u>					
DATE	TIME	APPEARANCE-FRONT	APPEARANCE-REAR	DISP	BY
11/17/07	4:25pm	A	A	P	Scm
11/18/07	7:20Am	A	A	P	Scm BSR
11/18/07	8:20Am	A	A	P	BSR Scm
11/18/07	11:30Am	A	A	P	BSR Scm
11/18/07	12:30pm	A	A	P	Scm BSR
11/18/07	1:30pm	A	A	P	BSA Scm
11/18/07	2:30pm	A	A	P	Scm BSR
11/18/07	3:30pm	A	A	P	Scm
11/18/07	4:00pm	A	A	P	Scm
11/19/07	7:50Am	A	A	P	BSR
11/19/07	8:50Am	A	A	P	BSR Scm
11/19/07	9:50Am	A	A	P	BSR Scm
11/19/07	11:00Am	A	A	P	NUM
11/19/07	12:00pm	A	A	P	BSR Scm
11/19/07	1:00pm	A	A	P	NUM
11/19/07	2:40pm	A	A	P	Scm
11/19/07	6:55PM	A	A	P	mmr
11/20/07	7:45Am	A	A	P	NUM
11/20/07	8:45Am	A	A	P	mmr BSR
11/20/07	9:25Am	A	A	P	mmr
11/20/07	11:00Am	A	A	P	BSR
11/20/07	12:00pm	A	A	P	BSR Scm
11/20/07	1:00pm	A	A	P	NUM
		N/A	Scm 11/20/07		

REV. BY Scm 11/20/07

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ACTAV 000002626

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Actavis Totowa LLC

COMPRESSION DATA SHEET

Page 1 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/17/07 SPC
11/18/07 11/17/07Tablet Press Id: Hardness Tester Id: 251 Thickness Gauge Id: 967 Scale Id: 1156

Target Weight (1 Tablet): 1.050 mg

Thickness: 2.0 - 3.0 mm

Target Weight (10 Tablets): 1.050 g

Hardness: 1.0 - 6.0 KP

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

OF 7

Every 30 minutes, check ten (10) tablets for aggregate weight and appearance and three (3) tablets for hardness and thickness from each exit chute of the tablet press and compare results to the above product specifications. Record RPM of tablet press upon stabilization of press after every startup, and speed changes

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
	MIC	start	UP						SPG										
PM 3:20	1.066	OK	2.71	2.73	2.68	4.2	3.8	4.0	SPG	PM 3:20	1.062	OK	2.70	2.71	2.74	4.0	3.9	3.5	SPG
	Exit	sy	check						SPG										
	MIC	stop	FOR QA	Approval					SPG										
	MIC	start	AFTER QA	Approval					SPG										
PM 4:10	1.055	OK	2.71	2.68	2.68	4.2	3.9	4.2	SPG	PM 4:10	1.065	OK	2.71	2.70	2.69	4.1	4.5	3.7	SPG
4:40	1.068	OK	2.69	2.73	2.68	3.8	4.6	4.0	SPG	4:40	1.049	OK	2.66	2.70	2.69	4.2	3.8	3.6	SPG
4:50	MIC	stop	FOR	End of Shift					SPG										
	MIC	Start	UP	11/18/07					AV										
Date	SPG 11/17/07					Comments:													
Time	PM 4:15																		
RPM	22																		

*App = Appearance

14504-08

ACTAV 000002627

COPY

11/18/07 11/17/07

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Actavis Totowa LLC

COMPRESSION DATA SHEET

Page 2 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/18/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
7:30 AM	1.066	OK	2.73	2.68	2.71	4.0	4.0	4.2	AV	7:30 AM	1.040	OK	2.68	2.70	2.67	3.1	3.4	3.7	AV
8:00	1.055	OK	2.71	2.69	2.65	3.3	3.8	4.2	AV	8:00	1.051	OK	2.69	2.71	2.68	3.9	3.6	3.7	AV
8:30	1.043	OK	2.69	2.62	2.65	3.8	4.2	4.0	AV	8:30	1.047	OK	2.68	2.73	2.70	4.3	3.7	4.0	AV
9:00	1.044	OK	2.67	2.66	2.67	3.9	4.0	3.7	AV	9:00	1.047	OK	2.64	2.65	2.65	3.6	4.0	4.3	AV
9:30	1.048	OK	2.69	2.67	2.68	3.8	4.4	4.0	AV	9:30	1.048	OK	2.67	2.66	2.66	4.0	4.0	4.1	AV
10:00	1.052	OK	2.64	2.68	2.69	4.7	4.3	4.2	AV	10:00	1.051	OK	2.73	2.67	2.69	4.5	4.3	3.8	AV
10:30	1.055	OK	2.70	2.65	2.70	3.7	3.7	4.4	AV	10:30	1.043	OK	2.64	2.63	2.68	4.3	3.9	3.9	AV
11:00	1.043	OK	2.69	2.64	2.66	4.2	4.1	4.7	AV	11:00	1.064	OK	2.69	2.67	2.69	4.8	4.1	4.5	AV
11:30	1.052	OK	2.69	2.62	2.62	4.3	3.8	3.8	AV	11:30	1.054	OK	2.64	2.65	2.64	4.7	4.6	4.3	AV
12:00 PM	1.047	OK	2.63	2.66	2.65	4.0	4.1	4.3	AV	12:00 PM	1.054	OK	2.66	2.67	2.65	4.4	4.3	4.5	AV
12:30	1.042	OK	2.64	2.65	2.63	4.1	5.0	4.1	AV	12:30	1.051	OK	2.63	2.68	2.64	4.0	4.2	4.1	AV
12:50	m/c stop Break																		
1:10	1.048	OK	2.63	2.64	2.63	4.2	4.1	3.9	AV	1:10	1.045	OK	2.71	2.62	2.61	3.6	4.2	4.2	AV
1:40	1.047	OK	2.66	2.68	2.66	4.4	4.2	4.5	AV	1:40	1.045	OK	2.66	2.65	2.66	3.9	4.0	3.9	AV
Date	11/18/07					Comments:													
Time	7:40 AM																		
RPM	22																		

*App = Appearance

-14504-08

ACTAV 000002628

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Actavis Totowa LLC

COMPRESSION DATA SHEET

Page 3 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/19/07

Target Weight (10 Tablets): 1.050 g
Tablet Press Speed: 14 - 28 rpm

Weight Range (10 Tablets): 1.019 - 1.082 g

Front Exit Chute										Rear Exit Chute									
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
2:10 PM	1.055	OK	2.67	2.71	2.69	3.9	4.3	4.6	AV	2:10 PM	1.046	OK	2.67	2.66	2.64	4.3	3.9	3.6	AV
2:40	1.041	OK	2.61	2.66	2.64	4.1	3.7	4.3	AV	2:40	1.053	OK	2.67	2.71	2.70	4.0	4.4	4.1	AV
3:10	1.067	OK	2.69	2.67	2.66	4.3	4.1	4.2	SKR	3:10	1.066	OK	2.69	2.68	2.66	4.3	4.0	4.0	SKR
3:40	1.060	OK	2.63	2.66	2.64	4.1	4.0	3.8	SKR	3:40	1.055	OK	2.65	2.60	2.63	4.8	4.1	4.7	SKR
4:10	1.054	OK	2.68	2.65	2.61	4.0	3.8	4.1	SKR	4:10	1.061	OK	2.68	2.70	2.66	4.0	4.4	4.1	SKR
4:40	1.058	OK	2.66	2.70	2.67	4.1	4.4	3.9	SKR	4:40	1.065	OK	2.61	2.66	2.68	4.3	4.4	4.0	SKR
4:52	m/c STOP END OF SHIFT																		
	m/c	start	4p						AV										
7:50 AM	1.065	OK	2.77	2.72	2.74	3.8	3.9	3.9	AV	7:50 AM	1.066	OK	2.74	2.72	2.74	3.7	4.2	4.3	AV
8:20	1.060	OK	2.74	2.68	2.66	4.3	4.2	3.8	AV	8:20	1.059	OK	2.69	2.73	2.67	4.1	4.0	3.9	AV
8:50	1.054	OK	2.68	2.72	2.65	3.7	3.8	4.3	AV	8:50	1.063	OK	2.68	2.69	2.67	4.3	4.1	4.3	AV
9:20	1.056	OK	2.71	2.72	2.69	4.1	4.0	3.7	AV	9:20	1.064	OK	2.68	2.73	2.69	4.1	4.2	3.9	AV
9:50	1.068	OK	2.70	2.68	2.69	4.2	4.2	4.4	AV	9:50	1.054	OK	2.68	2.64	2.67	4.0	3.9	4.0	AV
10:20	1.053	OK	2.68	2.68	2.71	3.7	4.4	4.0	AV	10:20	1.068	OK	2.70	2.68	2.72	4.6	4.2	4.3	AV
Date	11/19/07					Comments:													
Time	2:28 PM																		
REP	22																		

*App = Appearance

<14504-08>

ACTAV 000002629

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Actavis Totowa LLC

COMPRESSION DATA SHEET

Page 4 of 5

Prod Id: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Batch #: 70924A

Date: 11/19/07

Target Weight (10 Tablets): 1.050 g

Weight Range (10 Tablets): 1.019 - 1.082 g

Tablet Press Speed: 14 - 28 rpm

COPY

Front Exit Chute									Rear Exit Chute										
Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init	Time	Weight (g)	App *	Thickness 2.0 - 3.0 mm			Hardness 1.0 - 6.0 KP			Init
10:28 ^{AM}	m/c	STOP	FOR Break						AV										
11:00	1.068	OK	2.66	2.70	2.68	4.0	4.0	4.7	AV	11:00	1.064	OK	2.70	2.72	2.72	5.1	4.1	4.7	AV
11:30	1.042	OK	2.66	2.64	2.64	4.0	4.1	4.4	AV	11:30	1.060	OK	2.66	2.71	2.65	4.4	3.8	3.9	AV
12:00 ^{PM}	1.041	OK	2.63	2.66	2.62	4.8	4.2	4.8	AV	12:00 ^{PM}	1.062	OK	2.67	2.68	2.65	4.6	4.2	4.3	AV
12:30	1.051	OK	2.64	2.65	2.64	4.7	4.4	4.3	AV	12:30	1.041	OK	2.65	2.66	2.69	4.2	3.7	4.5	AV
1:00	1.041	OK	2.62	2.65	2.66	4.4	4.3	4.4	AV	1:00	1.048	OK	2.65	2.68	2.71	4.5	3.9	4.0	AV
1:28	m/c	STOP	FOR Lunch Break						AV										
2:10	1.056	OK	2.68	2.70	2.66	5.1	4.6	5.1	AV	2:10	1.052	OK	2.68	2.74	2.69	3.9	4.0	4.2	AV
2:40	1.064	OK	2.68	2.65	2.65	4.0	4.4	4.6	AV	2:40	1.054	OK	2.70	2.68	2.69	4.5	4.5	4.3	AV
3:10	1.065	OK	2.69	2.67	2.68	4.4	4.2	5.1	AV	3:10	1.059	OK	2.67	2.68	2.65	4.7	4.9	4.8	AV
3:40	1.055	OK	2.64	2.66	2.68	4.1	4.4	3.9	AV	3:40	1.061	OK	2.71	2.75	2.70	3.8	4.3	4.1	AV
3:55 ^{PM}	m/c STOP								PM										
6:20 ^{PM}	1.068	OK	2.67	2.71	2.72	4.3	4.7	4.2	PM	6:20 ^{PM}	1.066	OK	2.72	2.70	2.73	4.2	4.5	4.1	PM
6:50	1.066	OK	2.68	2.69	2.70	4.4	4.5	4.7	PM	6:50	1.060	OK	2.66	2.68	2.67	4.4	4.3	4.5	PM
Date	11/19/07					Comments:													
Time	11:15 ^{AM}																		
RPM	22																		

*App = Appearance

c14504-08

ACTAV 000002630

COPY

32-469
10/15/08

Amide Pharmaceutical, Inc.
QA In-Process Compression Start Up Data Sheet

not 01/25/08
COPY 67
1.25.08

Product: Digoxin Tablets, 0.125 mg		Batch Number: 70924A
Number of Stations: 45		Side: FRONT
Appearance: A	MPR #: 14504-08	
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared Verified By: Asp / Scm Date: 11/17/07 11/17/07		

	Weight	Thickness	Hardness
1	0.102	2.75	3.5
2	0.106	2.78	3.8
3	0.104	2.69	3.2
4	0.108	2.73	3.4
5	0.105	2.72	4.3
6	0.107	2.76	3.4
7	0.105	2.75	3.6
8	0.105	2.78	4.0
9	0.107	2.72	3.8
10	0.109	2.72	3.5
11	0.107	2.75	4.2
12	0.108	2.72	3.9
13	0.104	2.75	4.3
14	0.108	2.73	3.4
15	0.110	2.75	3.2
16	0.105	2.77	3.2
17	0.109	2.80	4.1
18	0.105	2.75	3.9
19	0.107	2.74	3.8
20	0.106	2.76	3.9
21	0.105	2.75	3.8
22	0.108	2.72	3.9
23	0.107	2.69	4.0
24	0.107	2.73	3.7
25	0.108	2.74	3.7

	Weight	Thickness	Hardness
26	0.107	2.69	3.6
27	0.104	2.69	3.4
28	0.101	2.74	3.8
29	0.105	2.65	3.5
30	0.109	2.70	4.1
31	0.102	2.69	3.5
32	0.109	2.71	3.7
33	0.104	2.70	3.6
34	0.105	2.73	3.9
35	0.103	2.72	3.8
36	0.108	2.68	4.2
37	0.101	2.70	4.0
38	0.104	2.69	3.7
39	0.111	2.71	3.4
40	0.105	2.71	3.4
41	0.105	2.72	3.6
42	0.110	2.70	3.5
43	0.106	2.68	4.0
44	0.109	2.69	3.9
45	0.104	2.71	3.7
46			
47			Scm
48	N/A		11/20/07
49			
50			

Disposition: Pass
Analyzed By: Asp / Scm
Reviewed By: Scm

Time: 4:05 PM
Date: 11/17/07 11/17/07
Date: 11/20/07

Comments: N/A Scm 11/20/07

Digoxin 0.125 mg Data F.00

Amide Pharmaceutical, Inc.
QA In-Process Compression Start Up Data Sheet

2006 01/25/08
GOP 35
p. 324/67
Jed

Product: Digoxin Tablets, 0.125 mg		Batch Number: 70924A 01/15/08
Press #: 71	Number of Stations: 45	Side: REAR
Appearance: A	MPR #: 70924A	
Specifications		
Weight (Th. 0.105 g) (0.097 - 0.113) g	Thickness (2.00 - 3.00) mm	Hardness (1.0 - 6.0) kp
Compression Data Sheet signed / Equipment cleared Verified By: ASK/Scm Date: 11/17/07 11/20/07		

	Weight	Thickness	Hardness
1	0.108	2.74	4.1
2	0.107	2.75	4.1
3	0.106	2.73	4.1
4	0.106	2.75	4.7
5	0.108	2.74	3.8
6	0.109	2.75	4.2
7	0.110	2.72	3.9
8	0.107	2.79	3.9
9	0.106	2.74	3.7
10	0.107	2.74	3.9
11	0.110	2.77	4.0
12	0.109	2.72	3.8
13	0.109	2.70	4.0
14	0.110	2.74	4.1
15	0.108	2.71	4.3
16	0.106	2.76	4.0
17	0.107	2.71	3.8
18	0.109	2.70	4.1
19	0.108	2.76	4.6
20	0.107	2.71	4.1
21	0.108	2.72	4.0
22	0.110	2.72	3.9
23	0.107	2.71	4.5
24	0.110	2.73	4.3
25	0.107	2.71	4.1

	Weight	Thickness	Hardness
26	0.110	2.72	4.2
27	0.108	2.76	4.1
28	0.107	2.71	4.5
29	0.108	2.74	3.8
30	0.107	2.74	4.4
31	0.110	2.75	4.4
32	0.109	2.73	4.3
33	0.108	2.71	3.7
34	0.108	2.73	4.1
35	0.105	2.73	4.2
36	0.107	2.73	4.4
37	0.108	2.68	3.9
38	0.105	2.72	4.1
39	0.107	2.75	3.7
40	0.107	2.72	4.2
41	0.108	2.74	4.1
42	0.109	2.74	4.2
43	0.108	2.75	4.0
44	0.110	2.74	4.3
45	0.110	2.73	3.9
46	/		
47			
48			
49			
50			

Disposition: Pass
Analyzed By: ASK/Scm
Reviewed By: Scm

Time: 4:05 PM
Date: 11/17/07 11/20/07
Date: 11/20/07

Comments: N/A Scm 11/20/07

Digoxin 0.125 mg Data R.00

WEIGHT

BATCH 70924A

COPY

PRESS.NO 71

SIDE Front

THEO. 0.105gm

RANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 _{am}	0.108	0.107	0.107	0.106	0.107	0.104	0.107	0.107	0.108	0.106	P	Sam ASR
11/18/07	8:25 _{am}	0.105	0.106	0.107	0.105	0.104	0.107	0.109	0.104	0.105	0.105	P	Sam ASR
11/18/07	9:15 _{am}	0.107	0.103	0.106	0.103	0.106	0.106	0.107	0.104	0.102	0.102	P	Sam ASR
11/18/07	10:25 _{am}	0.106	0.104	0.105	0.104	0.105	0.103	0.104	0.105	0.103	0.104	P	Sam ASR
11/18/07	11:25 _{am}	0.103	0.107	0.103	0.105	0.104	0.109	0.102	0.108	0.109	0.103	P	Sam ASR
11/18/07	12:25 _{pm}	0.103	0.103	0.104	0.106	0.105	0.105	0.104	0.103	0.105	0.105	P	Sam ASR
11/18/07	1:25 _{pm}	0.103	0.101	0.105	0.104	0.106	0.103	0.102	0.107	0.102	0.105	P	Sam ASR
11/18/07	2:25 _{pm}	0.104	0.103	0.105	0.104	0.105	0.105	0.103	0.104	0.103	0.106	P	Sam ASR
11/18/07	3:25 _{pm}	0.105	0.105	0.108	0.102	0.107	0.106	0.103	0.104	0.107	0.107	P	Lee
11/18/07	4:10 _{pm}	0.104	0.106	0.108	0.105	0.107	0.105	0.106	0.107	0.106	0.106	P	Sam
11/19/07	8:00 _{am}	0.104	0.107	0.107	0.107	0.107	0.103	0.106	0.108	0.107	0.107	P	Sam ASR
11/19/07	9:00 _{am}	0.105	0.104	0.111	0.105	0.107	0.104	0.107	0.109	0.107	0.106	P	Sam ASR

REV Sam

DATE 11/20/67

197
11/15/03

Confidential

Amide Pharmaceutical, Inc.
QA IN - PROCESS COMPRESSION OVER CHECK DATA SHEET

THICKNESS / HARDNESS

PRODUCT Digoxin Tablets 0.125mg

COPY

BATCH 70 924APRESS NO 71SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE (2.0 --- 3.0) mm					RANGE (1.0 --- 6.0) kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 am	2.68	2.68	2.72	2.75	2.73	3.6	4.2	4.2	3.8	4.1	P	ASR Sam
11/18/07	8:25 am	2.70	2.67	2.70	2.72	2.70	4.5	4.1	4.2	3.7	4.0	P	ASR Sam
11/18/07	9:15 am	2.63	2.73	2.66	2.79	2.71	3.8	3.7	3.9	3.8	4.0	P	ASR Sam
11/18/07	10:25 am	2.66	2.68	2.66	2.72	2.71	3.4	3.4	4.0	4.6	4.5	P	ASR Sam
11/18/07	11:25 am	2.64	2.66	2.63	2.68	2.69	4.2	4.1	4.5	4.2	4.7	P	ASR Sam
11/18/07	12:25 pm	2.65	2.62	2.62	2.64	2.69	4.2	4.4	3.5	4.2	3.7	P	ASR Sam
11/18/07	1:25 pm	2.66	2.65	2.65	2.64	2.71	3.8	3.9	3.9	3.8	4.0	P	ASR Sam
11/18/07	2:25 pm	2.63	2.71	2.67	2.69	2.69	4.2	4.5	4.7	3.4	4.2	P	ASR Sam
11/18/07	3:25 pm	2.68	2.72	2.69	2.70	2.67	4.6	4.8	4.3	4.1	4.3	P	JAL
11/18/07	4:10 pm	2.69	2.67	2.70	2.68	2.71	4.9	4.7	4.7	4.9	3.8	P	SCM
11/19/07	8:00 am	2.73	2.72	2.70	2.82	2.77	4.0	4.1	4.0	4.0	4.2	P	ASR Sam
11/19/07	9:00 am	2.67	2.71	2.71	2.66	2.78	3.9	4.1	4.3	3.7	3.7	P	ASR Sam

REV. BY SamDATE 11/20/07

COPY

11/20/07

37

ACTAV 000002635

WEIGHT

BATCH 70924A

COPY

PRESS.NO 71

SIDE Rear

THEO. 0.105gm

RANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 AM	0.106	0.105	0.102	0.101	0.108	0.105	0.102	0.106	0.102	0.105	P	Scm ASL
11/18/07	8:25 AM	0.105	0.102	0.105	0.104	0.108	0.104	0.103	0.102	0.106	0.104	P	Scm ASL
11/18/07	9:15 AM	0.106	0.108	0.105	0.106	0.104	0.106	0.107	0.108	0.105	0.104	P	Scm ASL
11/18/07	10:25 AM	0.105	0.105	0.106	0.103	0.104	0.105	0.105	0.106	0.104	0.103	P	Scm ASL
11/18/07	11:25 AM	0.108	0.106	0.109	0.102	0.105	0.108	0.107	0.105	0.104	0.107	P	Scm ASL
11/18/07	12:25 PM	0.105	0.102	0.106	0.107	0.103	0.104	0.105	0.103	0.105	0.102	P	Scm ASL
11/18/07	1:25 PM	0.106	0.104	0.103	0.103	0.105	0.104	0.105	0.101	0.105	0.106	P	Scm ASL
11/18/07	2:25 PM	0.105	0.106	0.110	0.105	0.107	0.106	0.105	0.104	0.106	0.107	P	ASL Scm
11/18/07	3:25 PM	0.105	0.105	0.106	0.104	0.106	0.106	0.104	0.105	0.106	0.103	P	KL
11/18/07	4:10 PM	0.108	0.107	0.108	0.107	0.107	0.106	0.107	0.106	0.107	0.104	P	SLU
11/19/07	8:00 AM	0.109	0.105	0.108	0.106	0.106	0.106	0.106	0.107	0.108	0.107	P	ASL Scm
11/19/07	9:09 AM	0.107	0.105	0.106	0.109	0.106	0.107	0.108	0.105	0.107	0.107	P	ASL Scm

REV Sam

DATE 11/20/07

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P. 100
11/25/55

THICKNESS/ HARDNESS

COP^W

PRESS NO 71

SIDE Rear

		THICKNESS					HARDNESS						
		RANGE (2.0 ---- 3.0)mm					RANGE (1.0---6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/18/07	7:35 _{pm}	2.67	2.67	2.70	2.73	2.68	3.1	3.1	3.6	3.6	3.7	P	Scm ASR
11/18/07	8:35 _{pm}	2.64	2.65	2.64	2.63	2.67	3.2	4.3	3.6	4.0	3.9	P	ASR Scm
11/18/07	9:15 _{pm}	2.68	2.69	2.69	2.71	2.69	3.9	4.7	4.1	4.1	4.0	P	ASR Scm
11/18/07	10:25 _{pm}	2.67	2.74	2.69	2.66	2.68	4.5	4.6	4.5	3.9	4.2	P	Scm ASR
11/18/07	11:25 _{pm}	2.70	2.70	2.72	2.71	2.71	4.9	4.6	4.4	4.3	4.4	P	ASR Scm
11/18/07	12:25 _{pm}	2.68	2.72	2.66	2.66	2.66	4.0	4.2	4.2	4.3	3.6	P	ASR Scm
11/18/07	1:25 _{pm}	2.66	2.62	2.69	2.68	2.66	4.3	3.6	4.3	3.7	4.1	P	Scm ASR
11/18/07	2:25 _{pm}	2.68	2.68	2.64	2.65	2.65	4.3	4.7	4.2	4.5	4.3	P	Scm ASR
11/18/07	3:25 _{pm}	2.65	2.69	2.64	2.69	2.66	5.4	4.5	4.5	4.6	4.7	P	for
11/18/07	4:20 _{pm}	2.67	2.68	2.68	2.70	2.68	4.4	4.2	4.8	4.5	4.2	P	Scm
11/19/07	8:00 _{pm}	2.70	2.72	2.74	2.67	2.70	4.1	3.8	4.1	4.0	4.2	P	ASR Scm
11/19/07	9:00 _{pm}	2.70	2.72	2.71	2.70	2.73	4.1	4.5	4.3	4.6	4.0	P	ASR Scm

REV. BY Sam

DATE 11/20/07

11/25/28

WEIGHT

BATCH 70924A
702 ASK
11/15/03

COPY

RANGE 0.097 --- 0.113 gml

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 AM	0.105	0.106	0.106	0.104	0.109	0.107	0.108	0.104	0.107	0.107	P	ASR
11/19/07	11:10 AM	0.103	0.107	0.110	0.105	0.105	0.109	0.105	0.109	0.104	0.107	P	UM
11/19/07	12:10 PM	0.103	0.105	0.102	0.106	0.105	0.103	0.102	0.104	0.106	0.105	P	ASR
11/19/07	1:10 PM	0.107	0.105	0.105	0.106	0.104	0.107	0.105	0.104	0.106	0.105	P	UM
11/19/07	2:20 PM	0.105	0.106	0.107	0.107	0.106	0.105	0.104	0.105	0.107	0.107	P	Scm
11/19/07	3:25 PM	0.105	0.106	0.105	0.105	0.106	0.103	0.108	0.104	0.107	0.106	P	ASR
11/19/07	6:25 PM	0.105	0.104	0.105	0.103	0.103	0.107	0.104	0.103	0.106	0.108	P	ASR
11/19/07	7:30 PM	0.108	0.104	0.109	0.105	0.106	0.108	0.107	0.106	0.104	0.105	P	ASR
11/20/07	7:55 AM	0.104	0.110	0.107	0.108	0.106	0.109	0.106	0.109	0.106	0.107	P	UM
11/20/07	8:55 AM	0.105	0.103	0.101	0.109	0.107	0.108	0.105	0.107	0.107	0.108	P	ASR
11/20/07	9:55 AM	0.107	0.105	0.106	0.108	0.105	0.107	0.106	0.109	0.105	0.107	P	UM
11/20/07	11:10 AM	0.102	0.109	0.108	0.106	0.102	0.104	0.105	0.109	0.107	0.103	P	ASR

DATE 11/20/07

90-380167
JTB
01/15/08

THICKNESS / HARDNESS

COPY BATCH 70924A

SIDE FRONT

		THICKNESS					HARDNESS						
		RANGE (2.0 — 3.0)mm					RANGE (1.0 — 6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 AM	2.66	2.69	2.68	2.71	2.70	4.1	3.7	4.7	4.1	3.9	P	Scm ASR
11/19/07	11:10 AM	2.67	2.67	2.66	2.67	2.67	3.4	4.7	4.1	4.5	3.7	P	UM
11/19/07	12:10 PM	2.66	2.70	2.64	2.70	2.66	4.2	3.9	4.2	4.5	4.1	P	Scm ASR
11/19/07	1:10 PM	2.67	2.68	2.67	2.66	2.66	4.6	4.6	4.7	4.9	4.4	P	UM
11/19/07	2:20 PM	2.65	2.72	2.66	2.70	2.70	4.2	3.9	4.4	4.3	4.4	P	Scm
11/19/07	3:25 PM	2.69	2.67	2.66	2.63	2.67	4.4	4.7	4.2	4.4	4.2	P	Scm
11/19/07	6:25 PM	2.70	2.67	2.72	2.67	2.69	4.2	4.3	4.0	4.0	4.4	P	Scm ASR
11/19/07	7:30 PM	2.73	2.72	2.71	2.68	2.69	3.9	3.5	4.5	4.8	4.5	P	Scm ASR
11/20/07	7:55 AM	2.73	2.75	2.73	2.70	2.72	3.9	3.7	4.0	3.5	4.0	P	UM
11/20/07	8:55 PM	2.71	2.71	2.75	2.72	2.71	4.1	4.5	4.3	4.4	4.0	P	Scm ASR
11/20/07	9:55 AM	2.70	2.71	2.72	2.77	2.72	4.4	5.3	4.2	4.1	4.4	P	mmf
11/20/07	11:10 AM	2.69	2.70	2.74	2.68	2.70	4.3	3.6	4.4	4.2	4.4	P	Scm ASR

DATE 11/20/07

COPY

BR
11/201
25
10/7

WEIGHT

COPY

PRESS.NO 71

SIDE Rear

THEO. 0.105gm

RANGE 0.097 --- 0.113 gm

DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00am	0.104	0.105	0.107	0.104	0.104	0.105	0.107	0.107	0.106	0.105	P	Sam ASR
11/19/07	11:10Am	0.105	0.105	0.104	0.103	0.108	0.105	0.106	0.106	0.104	0.105	P	um
11/19/07	10:19pm	0.104	0.106	0.104	0.106	0.106	0.101	0.102	0.104	0.105	0.104	P	Sam ASR
11/19/07	1:10pm	0.103	0.107	0.107	0.107	0.106	0.105	0.110	0.103	0.108	0.106	P	um
11/19/07	2:20 Pm	0.107	0.108	0.106	0.107	0.107	0.104	0.106	0.105	0.105	0.103	P	Sam
11/19/07	3:25PM	0.104	0.104	0.108	0.104	0.105	0.105	0.104	0.107	0.103	0.106	P	te
11/19/07	6:25pm	0.105	0.107	0.105	0.103	0.105	0.105	0.103	0.104	0.107	0.103	P	Sam ASR
11/19/07	7:30pm	0.106	0.105	0.106	0.105	0.104	0.106	0.102	0.107	0.102	0.106	P	Sam ASR
11/20/07	7:55 AM	0.106	0.104	0.105	0.107	0.108	0.107	0.101	0.107	0.103	0.109	P	um
11/20/07	8:55 pm	0.104	0.103	0.108	0.102	0.105	0.104	0.106	0.103	0.106	0.104	P	um ASR
11/20/07	9:55 am	0.105	0.107	0.106	0.104	0.108	0.105	0.107	0.106	0.104	0.105	P	um ASR
11/20/07	11:10Am	0.103	0.107	0.107	0.108	0.103	0.105	0.105	0.105	0.109	0.103	P	um ASR

REV Sam

DATE 11/20/57

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P. 42 of 67
10/15/05

THICKNESS/ HARDNESS

Batch 70924A

SIDE Rear

COPY

		THICKNESS					HARDNESS						
		RANGE (2.0 ---- 3.0)mm					RANGE (1.0---6.0)kp						
DATE	TIME	1	2	3	4	5	6	7	8	9	10	DISP	BY
11/19/07	10:00 Am	2.68	2.68	2.66	2.70	2.72	3.7	4.0	4.3	4.2	3.7	P	Sam ASR
11/19/07	11:40 Am	2.67	2.68	2.67	2.65	2.66	4.0	4.0	3.8	4.2	3.7	P	QUM
11/19/07	12:10 Pm	2.63	2.66	2.66	2.70	2.63	3.8	3.7	3.5	4.4	4.1	P	Sam ASR
11/19/07	1:10 PM	2.69	2.67	2.67	2.68	2.68	3.8	4.9	4.1	4.6	4.1	P	QUM
11/19/07	2:20 Pm	2.68	2.69	2.71	2.66	2.65	3.7	3.9	4.6	4.0	4.7	P	Sam
11/19/07	3:25 PM	2.64	2.68	2.65	2.68	2.66	4.4	3.8	4.2	4.2	4.0	P	Har
11/19/07	6:25 Pm	2.69	2.69	2.69	2.70	2.74	5.0	3.7	4.2	4.0	4.5	P	Sam ASR
11/19/07	7:30 Pm	2.67	2.69	2.71	2.70	2.69	3.8	3.7	4.0	4.2	4.1	P	Sam ASR
11/20/07	7:55 AM	2.68	2.68	2.67	2.72	2.72	3.7	3.7	3.4	4.3	4.2	P	QUM
11/20/07	8:55 Pm	2.67	2.71	2.70	2.69	2.64	3.7	3.9	3.9	3.9	3.8	P	Sam ASR
11/20/07	9:55 AM	2.69	2.67	2.69	2.71	2.70	3.9	3.6	4.5	4.3	4.0	P	QUM
11/20/07	11:10 am	2.68	2.70	2.72	2.72	2.70	4.8	4.7	4.4	5.0	4.4	P	Sam ASR

DATE 11/20/07

80

04/25/05

1977

Actavis Totowa LLC

Attachment #3 **COPY COPY** *01/25/08*
01/25/08
FINISHED PRODUCT RELEASE - TEST REPORT

Product: Digoxin Tablets, USP 0.125 mg			
MOI #: 145	Revision #: 08	Product ID #: 145	Page 1 of 3
Prepared By: <i>Emerson Murphy</i>	Date: <i>03/19/07</i>	Approved By: <i>[Signature]</i> <i>04/04/07</i>	Effective Date: <i>07/12/07</i>

Batch # <i>70924A</i>

TEST (Source)	SPECIFICATION	RESULT	REFERENCE Volume/Page/ Chemist/Date
Description (In-house):	Yellow, round bisected tablets, debossed "A 145" or "B 145" on the bisected side	Yellow round, bisected tablets debossed "B145" on the bisected side	0162/50 DH 11/23/07
Identification A (USP):	The R _f value of the principal spot in the chromatogram of the sample solution corresponds to that of the standard solution.	conforms	0130/173 NPH 11/24/07
Identification B (USP):	The retention time of the major peak in the chromatogram of the sample solution corresponds to that of the standard solution obtained as directed in the HPLC assay test.	<p><i>RT (min)</i></p> <p><i>Std ≈ 11.0 min</i></p> <p><i>Assay ≈ 11.1 min</i></p> <p>conforms</p>	0045/1201 KHS 11.27.07

<input checked="" type="checkbox"/> COMPLIES	<input type="checkbox"/> DOES NOT COMPLY
--	--

REVIEWED	
BY: <i>JCS</i>	DATE: <i>11/28/07</i>

DATA APPROVAL	
By: <i>[Signature]</i>	Date: <i>11/28/07</i>

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Actavis Totowa LLC

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FINISHED PRODUCT RELEASE - TEST REPORT

Product: Digoxin Tablets, USP 0.125 mg			
MOI #: 145	Revision #: 08	Product ID #: 145	Page 2 of 3
Prepared By: <i>[Signature]</i>	Date: 03/14/07	Approved By: <i>[Signature]</i>	Effective Date: 07/12/07

Batch # 70924A

TEST (Source)	SPECIFICATION	RESULT		REFERENCE Volume/Page/ Chemist/Date
Friability (In-house):	NMT 1.0%	1. 0.02 % 0.0 %		0045/12.0/ KLS/11.27.07
Assay by HPLC (USP):	90.0% - 105.0%	96.0 %		0045/12.0/ KLS/11.27.07
Uniformity of Dosage Units by Content Uniformity (USP):	Acceptance Value ≤ 15.0 % (Meets USP <905> requirements)	1. 97.81	6. 96.91	0162/50 Dil 11/23/07
		2. 98.41	7. 95.41	
		3. 95.61	8. 96.31	
		4. 98.11	9. 95.81	
		5. 97.21	10. 95.91	
		Acceptance Value: 4.41		
Dissolution (USP): Apparatus: 1 (Basket) Medium: 0.1N HCl, 500 mL Temp: 37.0°C ± 0.5°C RPM: 120 Time: 60 minutes	NLT 80% (Q) dissolved in 60 minutes	1. 99 %	4. 97 %	0102/107 AEP 11/26/07
		2. 102 %	5. 101 %	
		3. 97 %	6. 98 %	
		Average: 99 %		

<input checked="" type="checkbox"/> COMPLIES	<input type="checkbox"/> DOES NOT COMPLY
--	--

REVIEWED
By: <i>[Signature]</i> DATE: 11/28/07

DATA APPROVAL
By: <i>[Signature]</i> DATE: 11/28/07

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FINISHED PRODUCT RELEASE - TEST REPORT

Product: Digoxin Tablets, USP 0.125 mg			
MOI #: 145	Revision #: 08	Product ID #: 145	Page 3 of 3
Prepared By: <i>Lamona Murphy</i>	Date: 03/19/07	Approved By: <i>Shallot</i> 03/27/07	Effective Date: 07/12/07

Batch # 70924A

TEST (Source)	SPECIFICATION	RESULT	REFERENCE Volume/Page/ Chemist/Date
Related Substances (In-house):			0045 12a/ KHS 11.27.07
Digoxigenin:	NMT 2.0%	EE 12H 11/27.07 0.35 0.37 %	
Digoxigenin Bisdigitoxoside:	NMT 2.0%	0.34 %	
Gitoxin:	NMT 3.0%	Not detected	0/30/1173 NPN 11/24/07

☒ COMPLIES☐ DOES NOT COMPLY

REVIEWED	
BY: <i>JCS</i>	DATE: 11/28/07

DATA APPROVAL	
By: <i>[Signature]</i>	Date: 11/28/07

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MPR #: 14504 Rev #: 08 Effective Date: 6/16/06

Batch #:

Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)

Batch Size: 4,800,000 Tablets

70924A

Page 18 of 24

OPERATING INSTRUCTIONS SECTION III
TABLET COMPRESSION MACHINE SET-UP

COPY

1. Check the required debossing for Amide or Bertek before issuing this part of the batch record and cross out the section of the batch record for the other debossing in Step # 2, Page # 18 and Step # 2, Page # 19.

AMIDE ~~(X)~~ K.V.P. 11/12/07 BERTEK (X)

Done By: K.V.P.	Date: 11/12/07	Checked By: [Signature]	Date: 11/16/07
-----------------	----------------	-------------------------	----------------

2. Install the following Punch and Die Set:

AMIDE:

Punch Set	Box #	Description
Upper Punch	44, 44A	1/4" Flat bevel round bisect punches embossed "A145"
Lower Punch	44, 44A	1/4" Flat bevel round punches
Die Set	44, 44A	1/4" round dies

BERTEK:

Punch Set	Box #	Description
Upper Punch	135, 138, 189	1/4" Flat bevel round bisect punches embossed "B145"
Lower Punch	44, 44A, 135, 138, 189	1/4" Flat bevel round punches
Die Set	44, 44A, 135, 138, 189	1/4" round dies

NOTE: When two to five consecutive batches of DIGOXIN TABLETS, USP 0.125 mg are compressed, record "N/A" ("Not Applicable") for the second to fifth batch in the Done By and Checked By sections.

Done By: C.S.	Date: 11/16/07	Checked By: AV	Date: 11/16/07
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COPY Page 19 of 24 6/15/08

MPR #: 14504	Rev #: 08	Effective Date: 6/15/06	Batch #:
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			70924A
Batch Size: 4,800,000 Tablets			

6/15/08

OPERATING INSTRUCTIONS SECTION IV
COMPRESSION

COPY

CAUTION: PLEASE USE GLOVES AND PROTECTIVE MASKS DURING OPERATION.
NOTIFY THE SUPERVISOR IMMEDIATELY IF YOU HAVE A HEADACHE, FEEL WEAK
OR PALPITATING.

1. Inspect for cleanliness of Production Room # 119, 120 and the following compression equipment.

Utensils (Stainless Steel Scoops, etc.)

Tablet Press #: 67 Mfr. & Model: Stokes BB2 # of Stations: 45

Deduster(s) #: 121 Scale #: 940 Metal Detector #: 583

Tablet Press #: 71 Mfr. & Model: Stokes BB2 # of Stations: 45

Deduster(s) #: 120 Scale #: 982 Metal Detector #: 582

Check the Production Room and Equipment Usage and Cleaning Logs for previous cleaning documentation, except utensils and scales.

1 MC
11/17/07

ROOM #	DONE BY	DATE	QA APPROVAL BY	DATE
119	AMZ SPG	11/17/07	ASR / UM	11/17/07 11/17/07
120	SPG	11/17/07	ASR / UM	11/17/07 11/17/07

2. Compress tablets with the following characteristics:

Description:

☐ AMIDE: Yellow, round tablets, and imprinted with 'A 145' on the scored side of the tablet. N/A KVP 11/12/07

☒ BERTEK: Yellow, round tablets, and imprinted with B 145 on the scored side of the tablet.

Target Weight (1 Tablet):	105.0 mg
Target Weight (10 Tablets):	1.050 g
Weight Range (10 Tablets):	1.019 - 1.082 g
Thickness:	2.0 - 3.0 mm
Hardness:	1.0 - 6.0 KP
Tablet Press Speed:	14 - 28 rpm

After the specifications are met, record the final values for the tablet weights, thickness, and hardness and indicate "Start-Up" on the Compression Data Sheet.

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Page 20 of 249 67

MPR #: 14504 Rev #: 08 Effective Date: 6/16/06

Batch #:

Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)

Batch Size: 4,800,000 Tablets

70924A

COMPRESSION

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After QA approval, compress the tablets with the above listed characteristics. Monitor the weight, hardness, and thickness at least every thirty (30) minutes and record the results onto the In-Process Compression Data Sheet.

MACHINE #	DONE BY	CHECKED BY	DATE	QA APPROVAL BY	DATE
67	SPG	SMP	11/17/07	Scm	11/17/07
71	SPG	SMP	11/17/07	Scm	11/17/07

3. Weigh the filled containers of tablets and record the gross and net weights on the "Container ID Label - Compressed Tablets" for each container and in the appropriate rows below.

	CNTNR. #	SCALE #	GROSS (kg)	TARE (kg)	NET (kg)	WEIGHED BY	DATE
67	1	940	16.00	1.00	15.00	AV	11/18/07
71	2	982	16.10	1.10	15.00	AV	11/18/07
67	3	940	16.02	1.02	15.00	AV	11/18/07
71	4	982	16.02	1.02	15.00	AV	11/18/07
67	5	940	16.10	1.10	15.00	AV	11/18/07
71	6	982	16.10	1.10	15.00	AV	11/18/07
67	7	940	16.02	1.02	15.00	AV	11/18/07
71	8	982	16.10	1.10	15.00	AV	11/18/07
67	9	940	16.02	1.02	15.00	SKR	11/18/07
71	10	982	16.00	1.00	15.00	AV	11/18/07
67	11	940	16.00	1.00	15.00	SKR	11/18/07
71	12	982	16.00	1.10	15.00	AV	11/18/07
67	13	940	16.00	1.00	15.00	AV	11/19/07

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MPR #: 14504 Rev #: 08 Effective Date: 6/11/06

Batch #:

Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)

Batch Size: 4,800,000 Tablets

70924A

COMPRESSION

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	CNTNR. #	SCALE #	GROSS (kg)	TARE (kg)	NET (kg)	WEIGHED BY	DATE	
mic	71	14	982	16.10	1.10	15.00	SKL	11/18/07
	67	15	940	16.00	1.00	15.00	AV	11/19/07
	71	16	982	16.10	1.10	15.00	SKL	11/18/07
	67	17	940	16.02	1.02	15.00	AV	11/19/07
	71	18	982	16.10	1.10	15.00	AV	11/19/07
	67	19	940	16.10	1.10	15.00	AV	11/19/07
	71	20	982	16.10	1.10	15.00	AV	11/19/07
	67	21	940	16.10	1.10	15.00	AV	11/19/07
	71	22	982	16.10	1.10	15.00	AV	11/19/07
	71	23	982	16.10	1.10	15.00	AV	11/19/07
	71	24	982	16.10	1.10	15.00	AV	11/19/07
	71	25	982	16.12	1.12	15.00	AV	11/19/07
	71	26	982	16.10	1.10	15.00	AV	11/19/07
	71	27	982	16.10	1.10	15.00	AV	11/20/07
	67	28	982	16.10	1.10	15.00	AV	11/20/07
	67	29	940	16.10	1.10	15.00	AV	11/20/07
	71	30	982	16.02	1.02	15.00	AV	11/20/07
	67	31	940	16.10	1.10	15.00	AV	11/20/07
	67	32	940	16.10	1.10	15.00	AV	11/20/07
	67	33	940	16.02	1.02	15.00	AV	11/20/07
	67	34	940	16.00	1.00	15.00	AV	11/20/07
	TOTAL				499.24	AV	11/20/07	

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MPR #: 14504	Rev #: 08	Effective Date: 6/16/06	Batch #:
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			70924A
Batch Size: 4,800,000 Tablets			

COMPRESSION

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4. Weigh the blend waste, if any, and tablet rejects in the Production Room # 119, ~~120~~ 120, 1.56 kg.

AV 11/20/07

Also, weigh the total quantity of QA samples withdrawn during compression, 0.200 kg.

Done By: AV	Date: 11/20/07	Checked By: pmt	Date: 11/20/07
-------------	----------------	-----------------	----------------

5. Usable Final Blend Weight in Step # 31, Page # 16, 503.25 kg.

Done By: KVP	Date: 11/21/07	Checked By: K.D	Date: 11/21/07
--------------	----------------	-----------------	----------------

6. Calculation of tablet compression yield:

Quantity of Tablets Produced (Step # 3)

$$\frac{\text{Quantity of Tablets Produced (Step \# 3)}}{\text{Final Blend Weight (Step \# 5)}} \times 100 = \% \text{ Yield}$$

$$\frac{499.24 \text{ kg}}{503.25 \text{ kg}} \times 100 = 99.20 \% \text{ Yield}$$

NOTE: The Yield should be within 95.0 - 101.0%. If the Yield is outside of 95.0 - 101.0%, notify the Department Supervisor and determine the cause of the variance.

REMARKS:

Done By: K.D	Date: 11/21/07	Checked By: pmt	Date: 11/21/07
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MPR #: 14504	Rev #: 08	Effective Date: 6/16/06	Batch #:
Product Name: DIGOXIN TABLETS, USP 0.125 mg (145)			70924A
Batch Size: 4,800,000 Tablets			

COMPRESSION

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7. Production Management review and approval of the batch record.

Done By:	K.D.	Date:	11/21/07
Done By:	ELR	Date:	11/21/07

8. Quality Assurance compressed tablets approval and review of the batch record.

QA Approval By:	Stm	Date:	11/28/07
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EQUIPMENT USAGE AND CLEANING LOG

EQUIPMENT DESCRIPTION: STOKES TABLET PRESS
RR2-455tEQUIPMENT ID NUMBER: 67

PRODUCT NAME (#)	BATCH NUMBER	DATE & TIME BATCH STARTED	DATE & TIME BATCH COMPLETED	TYPE OF CLEAN (WET/DRY) DOI/REV #	DATE/TIME CLEANING STARTED	DATE/TIME CLEANING COMPLETED	CLEANED BY DATE	CHECKED BY DATE
<i>(146)</i> Digoxin Tablets USP 0.25mg (146)	70817A	10/28/07	10/28/07	DRY	10/28/07	10/28/07	SPB	pmc
Digoxin Tablets USP 0.25mg (146)	70832A	10/28/07	10/31/07	DRY	10/31/07	10/31/07	CK	NMP
Digoxin Tablets USP 0.25mg (146)	70833A	10/31/07	11/03/07	WET	11/03/07	11/03/07	SMP	pmc
Digoxin Tablets USP 0.25mg (146)	70834A	11/04/07	11/07/07	DRY	11/07/07	11/07/07	SMP	pmc
Digoxin Tablets USP 0.25mg (146)	70835A	11/13/07	11/13/07	DRY	11/13/07	11/13/07	SPB	NMP
Digoxin Tablets USP 0.25mg (146)	70836A	11/13/07	11/15/07	Wet	11/15/07	11/16/07	AS	pmc
Digoxin Tablets USP 0.125mg (145)	70924A	11/20/07	11/20/07	DRY	11/20/07	11/20/07	AS	pmc
Digoxin Tablets USP 0.125mg (145)	70925A	11/21/07	11/21/07	Wet	11/21/07	11/21/07	SPB	pmc

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Totowa LLC

Quality Assurance

Digoxin Tablets 0.125mg
Lot 70924A1 100% Inspection Protocol
(Investigation 07-093)

Overview:

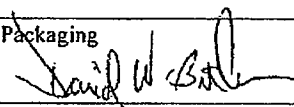
During the packaging and filling operation of batch 70924A1, two tablets of Digoxin 0.125 mg were observed with approximately double the thickness. Packaging operators inspected the tablets in the hopper as well as two subsequent product buckets for thicker tablets and found a total of five thicker tablets during the inspection. Quality Assurance subsequently put the batch on HOLD (H07-089) and investigation 07-093 was initiated.

According to this protocol, a 100% inspection on all tablets of the subject batch will be conducted at the Taft Road facility. Since the tablets have already been packaged, the bottles will need to be emptied and the bulk tablets 100% inspected.

A total of 4722 bottles of 1000 count tablets have been packaged which equates to approximately 4,722,000 tablets. Container ID labels for the bulk product and line ID labels will be issued by Documentation.

This inspection is being performed to ensure that all defect tablets have been removed from the batch. The type of defect to be inspected for will be reviewed with the inspectors. All tablets that are found to be double the thickness will be reported and rejected. Upon completion of this protocol, an AQL sample protocol will be written for Quality Assurance to evaluate the effectiveness of the 100% inspection.

Approved By:

Packaging  Quality Assurance	Date: _____ Date: 01/11/08
---	-------------------------------

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Totowa LLC

Quality Assurance

Digoxin Tablets 0.125mg
Lot 70924A1 100% Inspection Protocol
(Investigation 07-093)

Overview:

During the packaging and filling operation of batch 70924A1, two tablets of Digoxin 0.125 mg were observed with approximately double the thickness. Packaging operators inspected the tablets in the hopper as well as two subsequent product buckets for thicker tablets and found a total of five thicker tablets during the inspection. Quality Assurance subsequently put the batch on HOLD (H07-089) and investigation 07-093 was initiated.

According to this protocol, a 100% inspection on all tablets of the subject batch will be conducted at the Taft Road facility. Since the tablets have already been packaged, the bottles will need to be emptied and the bulk tablets 100% inspected. A total of 4722 bottles of 1000 count tablets have been packaged which equates to approximately 4,722,000 tablets. Container ID labels for the bulk product and line ID labels will be issued by Documentation.

This inspection is being performed to ensure that all defect tablets have been removed from the batch. The type of defect to be inspected for will be reviewed with the inspectors. All tablets that are found to be double the thickness will be reported and rejected. Upon completion of this protocol, an AQL sample protocol will be written for Quality Assurance to evaluate the effectiveness of the 100% inspection.

Approved By:

A. H. H. H. H.

Packaging

Date: 01/11/08

Date:

Quality Assurance

P.01

Jan 11 2008 16:55

Fax: 19738907980

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01/18/08

36
1/18/08
01/25/08

Digoxin Tablets 0.125mg
Lot 70924A1 100% Inspection Protocol
(Investigation 07-093)

Total Bulk Inspected:

- 33 Full Drums X 15.00 KG = 495.00 KG
- 1 Partial Drum X 3.48 KG = 3.48 KG
- Total 498.48 KG

Use form # F-PRD-219-A-00 for documenting "Inspected By"

Inspection Results Reviewed By:

AR Date: 01/18/08
QA Packaging
Samuel W. B. B. Date: 01/19/08
Quality Assurance Director

ACTAVIS TOWNA LLC Fax: 19738907980 Jan 11 2008 18:59 P.02

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Digoxin Tablets 0.125 mg (Lot # 70924A1)

BULK WEIGHT DOCUMENTATION

Jab
01/25/0858
P-36 of 67
Jab
01/25/08

BUCKET #	GROSS WT	TARE WT	NET WT
1	16.00	1.00	15.00
2	16.00	1.00	15.00
3	16.00	1.00	15.00
4	16.00	1.00	15.00
5	16.00	1.00	15.00
6	16.00	1.00	15.00
7	16.00	1.00	15.00
8	16.00	1.00	15.00
9	16.00	1.00	15.00
10	16.00	1.00	15.00
11	16.08	1.08	15.00
12	16.08	1.08	15.00
13	16.08	1.08	15.00
14	16.08	1.08	15.00
15	16.08	1.08	15.00
16	16.00	1.00	15.00
17	16.00	1.00	15.00
18	16.00	1.00	15.00
19	16.00	1.00	15.00
20	16.00	1.00	15.00
21	16.08	1.08	15.00
22	16.00	1.00	15.00
23	16.00	1.00	15.00
24	16.08	1.08	15.00
25	16.00	1.00	15.00
26	16.00	1.00	15.00
27	16.00	1.00	15.00
28	16.08	1.08	15.00
29	16.08	1.08	15.00
30	16.08	1.08	15.00
31	16.00	1.00	15.00
32	16.08	1.08	15.00
33	16.08	1.08	15.00
34	4.56	1.08	3.48
35			

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 01/15/08
 PAGE # 1 OF 1

 59
 1.20/67
 01/15/08
On Line Product Inspection Form

Product Name(#): <u>Digoxin Tablets 0.125mg (145)</u> Batch #: <u>70924A)</u>	
Area # <u>408</u>	
Observation:	
Observed By: _____ Date: _____ Production Management: _____ Date: _____	
Action to be taken:	
<p style="text-align: center;"> <i>N/A</i> <i>See attached</i> <i>Prot</i> <i>DMS</i> <i>01-15-08</i> </p>	
Production Management: _____ Date: _____ QA Approval: _____ Date: _____	
1. Check for cleanliness Production Room/Area and Utensils as per requirement. Room/ Area # <u>408</u> Done By: <u>JHR</u> Date: <u>01/15/08</u> Checked By: <u>M.D.S.</u> Date: <u>01/15/08</u> QA Approval By: <u>SPK</u> Date: <u>01/15/08</u>	
2. Inspect the Tablets/Capsules on the stainless steel trays covered with parchment paper. Done By: <u>PYD</u> Date: <u>01/15/08</u> Checked By: <u>JHR</u> Date: <u>01/15/08</u> Weight of Rejects: <u>0.08</u> Kg	
Management Comment: <u>Total of 15 Tablets with Approx. double the thickness were removed during inspection of this batch. The removed tablets are attached with this protocol.</u>	
Production Management: <u>DMS</u> Date: <u>01-18-08</u> QA Approval: <u>Wafu</u> Date: <u>01/18/08</u>	

1/15/2008

F-PRD-219.B.00

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Actavis
Totowa LLC

Quality Assurance

Digoxin Tablets 0.125mg
Lot 70924A1 Tightened AQL Inspection
(Investigation 07-093)

I. Overview:

During the packaging and filling operation of batch 70924A1, two tablets of Digoxin 0.125 mg were observed with approximately double the thickness. Packaging operators inspected the tablets in the hopper as well as two subsequent product buckets for thicker tablets and found a total of five thicker tablets during the inspection. Quality Assurance subsequently put the batch on HOLD (H07-089).

According to a QA provided inspection protocol, batch 70924A1 was 100% inspected by the packaging department for thicker tablets. The inspection criterion were reviewed with the inspectors prior to the inspection to ensure the acceptability of the product for release to the market. The inspection was completed and a total of 15 tablets with approximately double the thickness were removed from the entire batch. This is in addition to five tablets removed during the packaging operation.

The QA team will conduct a high level tightened AQL inspection to ensure the defect tablets have been removed from the batch.

II. AQL Sample Plan:

Digoxin Tablets 0.125mg have a theoretical batch size of 4,800,000 tablets.

The AQL sample will be pulled by QA based on the following:

- AQL level = 0.065
- Sample plan = single, tightened level I
- Sample Size Code = Q
- Bulk size = Approximately 4,747,428 (4,800,000 Theoretical)
- Inspect 1250 tablets (minimum)
 - 40 tablets will be inspected from the 33 full drums (1320 tablets)
 - 10 tablets will be inspected from the 34th drum (1/5 full)
 - Tablets will be taken randomly from each drum
- Accept on 1 / Reject on 2 (total for batch)

Approved By:

Packaging

Date:

Quality Assurance

Date:

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Digoxin Tablets 0.125mg
 Lot 70924A1 Tightened AQL Inspection
 (Investigation 07-093)

6/25/08

6/25/08

BATCH NUMBER	NUMBER OF TABLETS INSPECTED	NUMBER OF TABLETS WITH DEFECTS	TYPE OF DEFECT	INSPECTED BY DATE
1	40	0	None	AR 01/22/08
2	40	0	None	AR 01/22/08
3	40	0	None	AR 01/22/08
4	40	0	None	AR 01/22/08
5	40	0	None	AR 01/22/08
6	40	0	None	AR 01/22/08
7	40	0	None	AR 01/22/08
8	40	0	None	AR 01/22/08
9	40	0	None	AR 01/22/08
10	40	0	None	AR 01/22/08
11	40	0	None	AR 01/22/08
12	40	0	None	AR 01/22/08
13	40	0	None	AR 01/22/08
14	40	0	None	AR 01/22/08
15	40	0	None	AR 01/22/08
16	40	0	None	AR 01/22/08

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ACTAV 000002616

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Digoxin Tablets 0.125mg
 Lot 70924A1 Tightened AQL Inspection
 (Investigation 07-093)

DRUM NUMBER	NUMBER OF TABLETS INSPECTED	NUMBER OF TABLETS DEFECTS	TYPE OF DEFECT	INSPECTED BY DATE
17	40	0	NONE	AR 01/22/08
18	40	0	NONE	AR 01/22/08
19	40	0	NONE	PBP 01/22/08
20	40	0	NONE	PBP 01/22/08
21	40	0	NONE	AR 01/22/08
22	40	0	NONE	AR 01/22/08
23	40	0	NONE	AR 01/22/08
24	40	0	NONE	PBP 01/22/08
25	40	0	NONE	AR 01/22/08
26	40	0	NONE	AR 01/22/08
27	40	0	NONE	PBP 01/22/08
28	40	0	NONE	AR 01/22/08
29	40	0	NONE	AR 01/22/08
30	40	0	NONE	PBP 01/22/08
31	40	0	NONE	PBP 01/22/08
32	40	0	NONE	AR 01/22/08
33	40	0	NONE	AR 01/22/08
34	10	0	NONE	AR 01/22/08

Inspection Results Reviewed By:

QA Packaging

Quality Assurance Director

Date:

Date:

Confidential

ACTAV 000002617

Attachment # 8
Dues
01/25/08

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Dues
01/25/08

Is Totowa LLC

EQUIPMENT ID LABEL

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Prod ID: 145

Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Equipment Id: # 583

Equipment Name: Safe Line Metal Detector

Batch #: 70924A Manufacturing Start Date: 11/17/07

Manufacturing Stage/Dept: Compression

<14504-08>

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ACTAV 000002618

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Actavis Totowa LLC

METAL DETECTOR DATA SHEET

COPY

Page 1 of 1

Prod Id: 145 Prod Name: Digoxin Tablets, USP 0.125 mg Batch #: 70924A Date: 11/17/07
 Equipment I.D.: 583

- Step 1. Supervisor will set-up the Metal Detector and test. Supervisor signature verifies that sensitivity/threshold reading is correct. Record results in the proper column.
 Step 2. Operator confirms and records results in the proper column.
 Step 3. Operator will repeat the test at the beginning of each day and at the end of the run.

DATE	TIME (AM/PM) *	SUPERVISOR'S SIGNATURE	OPERATOR'S SIGNATURE	PASS	FAIL
11/17/07	3:40 AM (PM)	<i>pme</i>		✓	
11/17/07	3:42 AM (PM)		SPC	✓	
11/18/07	7:05 AM (PM)		AV	✓	
11/19/07	7:35 AM (PM)		AV	✓	
11/20/07	7:35 AM (PM)		AV	✓	
11/20/07	1:35 PM AM (PM)		AV	✓	
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				
	AM/PM				

* Circle AM/PM

SUPERVISOR REVIEW: K. D.DATE: 11/21/07

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by *11/17*
6/15/08

ACTAV 000002619

Confidential

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Totowa LLC

EQUIPMENT ID LABEL

COPY

Prod ID: 145 Prod Name: DIGOXIN TABLETS, USP 0.125 mg

Equipment Id: # 582

Equipment Name: Sqfeline Metal Detul Detector

Batch #: 70924A Manufacturing Start Date: 11/17/07

Manufacturing Stage/Dept: Compression

<14504-08>

ACTAV 000002620

Confidential

Actavis Totowa LLC

METAL DETECTOR DATA SHEET

COPY Page 1 of 1

Prod Id: 145 Prod Name: Digoxin Tablets, USP 0.125 mg Batch #: 70924A Date: 11/17/07
 Equipment I.D.: 582

- Step 1. Supervisor will set-up the Metal Detector and test. Supervisor signature verifies that sensitivity/threshold reading is correct. Record results in the proper column.
 Step 2. Operator confirms and records results in the proper column.
 Step 3. Operator will repeat the test at the beginning of each day and at the end of the run.

DATE	TIME (AM/PM) *	SUPERVISOR'S SIGNATURE	OPERATOR'S SIGNATURE	PASS	FAIL
11/17/07	3:10 AM/PM	P.M.			
11/17/07	3:17 AM/PM		SPC	✓	
11/18/07	7:20 AM/PM		AV	✓	✓
11/18/07	7:28 AM/PM		AV	✓	
11/19/07	7:46 AM/PM		AV	✓	
11/20/07	7:48 AM/PM		AV	✓	
11/20/07	11:30 AM/PM		AV	✓	
	AM/PM				
	AM/PM				
	AM/PM		AV 11/20/07		
	AM/PM				
	AM/PM				
	AM/PM				

* Circle AM/PM

SUPERVISOR REVIEW: k dDATE: 11/21/07

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ACTAV 00002621

11/21/07
 11/21/07
 11/21/07



Attachment #9
Jus 01/25/08

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Jus 01/25/08

TRAINING COMPLETION RECORD

SOP/Course Title: <u>Preventative Action training for Digoxin Tablets USP, 0.125mg Investigation # 07-093</u>		
Length of Time: <u>20</u> Hours/Minutes	Training Date: <u>01/24/08</u>	
SOP/DOI No.: <u>Investigation # 07-093</u>	Revision No.: <u>N/A</u> <u>01/24/08</u>	
Check all that apply: <input checked="" type="checkbox"/> On-The-Job-Training <input type="checkbox"/> Classroom Training <input type="checkbox"/> Revision/Refresher Training		

By signing this document, I am confirming that I have received the above training topic and that I understand how it relates to my job duties.

Training ID #	Print Name	Signature	Department
2000172	MAHENDAS PATEL	Mahendra Patel	Compression
2000151	Manubhai I. Patel	Manubhai Patel	Compression
2000138	Gordhambhai S. Patel	Gordhambhai Patel	Compression
2000311	Suryakant M. Patel	SM Patel	Compression
2000180	Prakash Patel	Prakash Patel	Compression
2000148	Chandrasekar R. Patel	CR Patel	Compression
2000241	Nirajesh Kumar N. Patel	N. Patel	Compression
2000617	Alexis Velez	Alexis Velez	Compression
2000223	Sunet B. Patel	Sunet Patel	Compression
2000603	Carlos Soto	Carlos Soto	Compression
2000189	Kim T. Patel	Kim T. Patel	Compression
2000218	Ashish M. Shah	Ashish Shah	Encapsulation
2000231	BHARAT K. PATEL	BK Patel	Compression
2000158	Suresh K. Patel	Suresh K. Patel	Compression

Comments:

☐ N/A

TRAINER

Print Name:	<u>K. V. Shah</u>	Dept #:	<u>Compression</u>
Signature:	<u>[Signature]</u>	Date:	<u>01/24/08</u>

TRAINING DOCUMENTATION GROUP USE ONLY

Computer Entry By: _____ (Signature/Date)
Session ID: _____